



Health Systems Strengthening

Rethinking the Role of Innovation

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Health Systems Strengthening **Rethinking the role of innovation**

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Globelics Thematic Report 2016

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Foreword

The Globelics network and its Secretariat (www.globelics.org) have committed to deliver an Annual Thematic Report that communicates important insights from research on innovation and development to stakeholders such as donor organisations and policy makers. Earlier reports have related innovation to respectively inclusive development, low-carbon development and natural resource-based development (see www.globelics.org/publications/globelics-thematic-review/).

The Globelics network was founded by economists linking innovation to economic development and catching-up. Increasingly, it has been broadened to include scholars with a sociological or political science background who come from related fields such as science and technology studies and other parts of the development studies field. The authors of this report are two such individuals. Margrethe and Rebecca are members of the AfricaLics Secretariat and, along with other researchers in the Globelics family, have brought important new perspectives to the network.

The diversity in the range of researchers in the Globelics network is reflected in the wide span of research approaches that characterises the contributions to the Globelics annual conferences. Globelics is one of the few networks where there is an ongoing dialogue and cross-fertilisation between innovation studies, development studies and science and technology studies. This report draws upon these different perspectives but the emphasis is especially on the latter two. This foreword introduces concepts and ideas that have been developed within socio-economic approaches to innovation as a background and inspiration for the analysis in this report.

Innovation studies give prominent attention to certain components of the health system. The pharmaceutical sector is the most research intensive of all industrial sectors and it is one where intellectual property rights play a major role (Yacoub, 2008, Rashmi, 2008). Countries where Research and Development is responsible for a high proportion of Gross National Product will typically host a big

pharmaceutical sector. The ongoing innovations in medical instruments give important insights in how new products come about in an interaction with advanced users and how they are sometimes even developed by the users themselves. Von Hippel (1976) refers to scientific instruments as one technology field where user innovations are frequent. And some of the new technologies that are seen as the ones that will dominate the future – genetic engineering and biotechnology – have so far found their most important and lucrative applications in the health sector. Having a strong industry that addresses the health sector may therefore be seen as constituting a national competitive advantage (Nogueira, Britto and Vargas, 2015).

Information and communication technologies have already transformed activities in the health sector making it possible to make more systematic use of data, and they might – together with nanotechnology and biotechnology – lead us toward a completely new understanding of human health and well-being where specific diseases are foreseen and treated before they actually become diagnosed. Again, keeping at the forefront in such technological areas may be seen as a way to establish a future national competitive advantage (Perez, 2014).

Therefore, there is a link between the ambitions of the national health system and the national competitiveness of the entire economy. A country with technologically advanced medical services offers an interesting market for producers of drugs and instruments. The link between domestic users and producers may reflect proximity

but it might also be the result of policy-led public procurement strategies. In the beginning of the new Millennium, China's political leadership signaled that from now on they would give priority to indigenous innovation. They promoted the use of public procurement because of the impact it would have (and indeed has had) on improving the dynamic capabilities of Chinese enterprises (Gu et al., 2008).

The production of pharmaceuticals and medical instruments are research intensive activities and therefore research policy is of special importance for the health system. At the same time, the fact that health is an important aspect of human well-being makes it legitimate for governments to allocate substantial resources to research. While there is a negative view on selective technology and industrial policy in the US, there is little doubt that the very substantial public support to health related research has been a major factor in supporting a strong industrial capacity in pharmaceutical companies in the US (Nelson, 1988, p. 321).

The importance of health technologies for competitiveness is reflected in international economic relations. Most global research takes place in high income countries and, given that much of it is supported by tax payers' money and addressing markets in the rich countries, the focus of the research is upon health related problems within the rich countries. As a response to the relative neglect of finding cures for diseases which place a heavy burden on low income countries in the Global South, specific programs that relate to specific ailments such as TB

and HIV/AIDS have been implemented. But the production of these drugs remains principally located in the high income countries and in a few low and middle income countries such as India and Cuba. One type of barrier for establishing more local production is the intellectual property regime that is part of the WTO rules. The US pharmaceutical sector has been instrumental in pushing the US government drive for global protection of intellectual property rights (Rasigan, Mbula and Ndabeni, 2013).

This report does not focus on how to develop domestic production capacity in drugs and instruments. In many low income countries, developing significant domestic production capacity in the pharmaceutical sector may be a challenge because the opportunities are limited and the barriers are too high to overcome. But for middle income countries with ambitions to engage in new technological fields such as combinations of information technology, nano-technology and biotechnology, developing domestic production capacities is an important issue. According to recent research on catching-up, engaging in the most rapidly changing technologies is one of the few ways to break out of the so-called middle income trap (Lee, 2013). For those countries, the national health system represents a potential for learning by interacting with competent users. For them, the design of global rules of intellectual property rights is critical for what options they should go for. All these issues have been covered in research presented at Globelics conferences (see Annex 2).

This year's Globelics Thematic Review draws on research findings presented at Globelics conferences and wider research by scholars within the network and beyond. It presents a research based framework for the design and management of national health systems in low income countries. The focus is on innovations that contribute to shaping, maintaining and renewing health systems that should be socially inclusive, well-functioning and coherent. The overriding perspective is on how such systems can be designed so that they contribute to the well-being of citizens. This has implications for defining the scope of the system – it goes beyond the treatment of diseases and includes preventive action. It also goes beyond a techno-economic perspective on innovation. The report gives special attention to the important role of social innovation and system design. The report makes a distinction between product innovation and social innovation. The conclusions and recommendations that are provided at the end of the report are relevant for public policy action including governments partnering with private and civic organisations.

In conclusion, it is obvious that the theoretical framework developed by neoclassical economists is too narrow when it comes to analysing the drivers, processes and outcomes of innovation and that evolutionary economics perspectives are more promising in this respect. When it comes to analysing the role of innovation in health systems in low income countries, evolutionary economics needs to be combined with the STS tradition link-

ing science and technology to societal issues with focus on the social and political processes that shape such systems.

This report provides an important starting point in terms of combining the two approaches, complementing the efforts of individual researchers and research groups within the Globelics community. I hope that the report will start a wider discussion in the health field on the role and function of innovation in strengthening health systems, but also that it will start new debates within the innovation field on the importance of a multidisciplinary approach.

Prof. Bengt-Åke Lundvall
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Preface

This report is the fourth in a series of Globelics Thematic Review reports prepared during the period 2011 to 2016. The objective of the Globelics Thematic Reviews is to communicate insights from the community of scholars in the Global Network for the Economics of Learning, Innovation, and Competence Building Systems (Globelics) to policy circles and development donor organisations.

The Globelics Thematic Reviews constitute a commitment made to the Swedish International Development Corporation (Sida) in connection with a 2011 grant for the Globelics Secretariat located at Aalborg University. The reviews give an overview of research outcomes related to a particular topic as well as reflections on policy implications. Previous reports have focused on innovation and development, innovation for low carbon energy development and innovation for natural resource management. This year's report focuses on health systems strengthening and the role of innovation.

Rebecca Hanlin and Margrethe Holm Andersen wrote the report, which also counts on contribu-

tions by Bengt-Åke Lundvall (foreword) and Joanna Chataway (post-script).

The report has been developed through a comprehensive desk review of current literature on health innovation research from within the global health field as well as from within the innovation studies field, especially the Globelics community. It has also benefitted from a consultative process with members of the Globelics community and those from outside the community providing comments and feedback on the report's ideas and drafts of the report. The report was developed over a 16-month period from March 2015 to July 2016.

Likewise, we would like to thank those reviewers (a mix of innovation scholars and health policy scholars) who found time to review earlier drafts of the report in September 2015 and in the first half of 2016. Particular thanks are due to Judith Sutz, Smita Srinivas and Louise Hansen for their in-depth and valuable comments. We are particularly grateful to Bengt-Åke Lundvall for challenging our thinking as the report was developed.

The authors are also thankful to Nina Kotschenreuther for editorial support and to Emil Axel Størner for the identification of Globelics Conference papers within the field of health and innovation.

We hope you will enjoy reading the report.

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Acronyms

ASHA	Accredited social health activist
COHRED	Council on Health Research for Development
DAH	Development assistance for health
DUI	Doing, using and interaction
EBP	Evidence based policy
GDP	Gross domestic product
GHIs	Global health initiatives
Globelics	Global Network for the Economics of Learning, Innovation, and Competence Building Systems
GoK	Government of Kenya
HIV/AIDS	Human immunodeficiency virus infection and acquired immune deficiency syndrome
HSS	Health systems strengthening
HSSF	Health Sector Services Fund
ICT	Information communication technology
IPRs	Intellectual property rights
MDGs	Millennium Development Goals
NCEs	New chemical entities
NHIF	National health insurance fund

NRHM	National rural health mission
PDPs	Product development partnerships
R&D	Research and development
RMNCH	Reproductive, maternal, neonatal and child health
Sida	Swedish International Development Agency
SDGs	Sustainable Development Goals
STI	Science, technology and innovation
SWAp	Sector-wide approach
TB	Tuberculosis
TRIPs	Trade related intellectual property rights
UHC	Universal health coverage
UNDP	United Nations development programme
UNICEF	United Nations children's fund
US	United States of America
WHO	World Health Organisation
WTO	World Trade Organisation



1. Introduction

In early 2016, the Gavi (the Vaccine Alliance, formerly known as the Global Alliance for Vaccines and Immunisation) announced it had signed an ‘advance market commitment’ with Merck to bulk purchase its Ebola vaccine, even before it has been licensed, to ensure stockpiles are available and ready for the next outbreak of the virus. In Sub-Saharan Africa, incidences of malaria have been drastically reduced due to the introduction of long lasting insecticide treated mosquito net coverage campaigns. As a result, four countries (Namibia, Eritrea, Togo and Mali) saw their post-neonatal death rates reduced by over 20% between 2001 and 2010 (Eisele et al., 2012). In Brazil, since the introduction of a universal health insurance scheme funded through general taxation in the late 1980s, the percentage of the population now able to access healthcare services is 70%. Similarly, in Thailand, an alternative government health insurance scheme has reduced the percentage of the population without healthcare coverage from 30% to less than 4% (WHO, 2010). Cuba is renowned for having one of the

best public health services in the world because of its system whereby all newly qualified doctors go to work in rural areas and its emphasis on preventive health (Keck and Reed, 2012). In India, a low cost prosthetic was invented in 1968 – the Jaipur foot – providing a low-cost prosthetic for those unable to pay for more elaborate alternatives. Some 1.3 million artificial limbs have been fitted – free – through the work of the Jaipur foot organisation, BMVSS, based in India (BMVSS, 2013). In a further case from India, the Aravind Eye Hospitals have developed a differential pricing system and a highly efficient organisational set up allowing them to provide high quality eye operations to the poor extremely quickly (Aravind Eye Care System, 2015). In the UK, the ‘Healthy Liverpool’ programme introduced in 2015 aims to tackle the massive burden on the national health service in its city (as a result of an increasingly elderly population and unhealthy lifestyles) by focusing on prevention and having health and social care organisations work together to find policy and programmatic solutions (Sim,

2015). Finally, in Finland, expectant mothers since 1949 have received a ‘baby box’ containing all the items they need to look after their newborn baby including its first crib – the box itself. This led to a rapid reduction in infant mortality in the country within the first 10 years of the boxes becoming routine part of pre-natal care (Kobayashi, 2013).

What do all of the above have in common? They are all examples of innovations that have been introduced and which have improved, or are expected to improve, health outcomes around the world, sometimes extremely quickly and effectively.

When most people think of innovations in the health arena, they think of new drugs or vaccines being developed; maybe of new improvements in health information systems. The above examples include a few such technological innovations. However, most of them involve the introduction of a new organisational approach or a new way of packaging and implementing healthcare. These are also forms of innovation; what can be termed ‘social innovations’ as opposed to merely technological product innovations.¹

1 In this report, we refer to a very black-and-white distinction of ‘technological product innovation’ on the one side and ‘social innovation’ on the other. We have done this deliberately, in line with current policy dialogue in the health sector, but recognise that this is not in line with much innovation thinking. Many innovation scholars have always seen elements of organisational and social innovation elements as being essential to successful technological innovation and therefore inseparable from any definition

Many governments in emerging economies have been focusing increasingly on developing effective innovation policies (Goedhuys et al., 2015) but there is also increasing awareness of the importance of this at a sectoral level. Innovation is increasingly recognised as crucial for better healthcare solutions and necessary if health outcomes are to be improved. Governments around the world are introducing innovation into health discussions. Some, such as Brazil, have developed national policies to promote the use of science, technology and innovation for health or, like South Africa, have developed dedicated biotechnology strategies with a strong emphasis on feedbacks into the healthcare system. In many high income countries, there is recognition of the need to focus more specifically on health innovation and particularly on ensuring that health innovations are developed and diffused into the healthcare system. Thus, in the UK, a reorganisation of the National Health Service in 2013 led to the creation of Academic Health Science Networks bringing together clinicians, academics and the private sector to develop and diffuse new technologies into the National Health Service.

These activities at a national sectoral level have occurred at the same time as discussions within the global health arena on the role of innovation for improved healthcare and health systems functioning. For example, the World Health Organisation (WHO) has emphasised the importance of inno-

of technological innovation. We discuss this in more depth in Chapter 3.

vation as one of the foundational stones of the building blocks of a health system (WHO, 2007). In another example, the Council on Health Research for Development (COHRED) has championed the importance of all forms of research and innovation in order to “deliver sustainable solutions to the health and development problems of people living in low and middle-income countries” (COHRED, 2013).

Part of the interest in health innovation has undoubtedly been the result of the ‘Gates effect’ (Okie, 2006). The rise in funding by the Bill and Melinda Gates Foundation in the area of health research has significantly enhanced the attention given to health product development. This coupled with the work of the Global Fund for AIDS, Tuberculosis (TB) and Malaria and that of Gavi, which both focus on encouraging access to medicines in low and middle income countries. These organisations resulted in a rise in investment by private and public research organisations, especially through what are known as ‘global health partnerships’ (Buse and Harmer, 2004), in new health product development (vaccines, drugs and diagnostics) or improved deployment of existing health products in low and middle income countries.

Unfortunately, the majority of the discussion around health innovations continues to be dominated by discussions on the need for new or improved health technologies including new (and often expensive) types of medicine; tangible health products that can be easily seen and understood. Less attention has been spent on the organisational

and process innovations – the social innovations – outlined in the first paragraph, which are also required to ensure that health outcomes are improved. This report argues that this is unfortunate and needs to change. Process, organisational and systems level innovations are, in fact, often what is needed to make healthcare systems function effectively; these social innovations are key to strengthening health systems.

The need to consider innovation in a broader context is the starting point of this report. Work from within the academic field of innovation and development studies provides evidence of the relevance of thinking more widely about the types of innovation that take place within health systems.

The second starting point for this report relates to the need to ensure a better connection between health and development issues and to do away with the silos and disconnects that exist in the international development and health policy fields at national, regional and global levels. Specifically, the disconnects revolve around the relationship between health and development and the best ways to promote both.

The relationship between health and development has been acknowledged for many years, most notably in the World Development Report 1993 (World Bank, 1993) and its follow-up in 2013, ‘Global Health 2035: A world converging within a generation’ (Jamison et al., 2013). It is recognised that good health provides opportunities for improved educational attainment and work efficiency (through reduced absenteeism) leading to better

possibilities to move out of poverty. On the other side of the argument, it is recognised that those with more economically stable households often have the ability to pay for better healthcare and therefore are less likely to be absent from school or work in the first place. Both reports conclude that it is wise to ‘Invest in Health’ to paraphrase the 1993 report.

Both of these reports have been controversial for various reasons, most notably for their focus on the economic side of the issues at the expense of the social and political constraints that influence the level of success of health policy implementation and subsequent healthcare provision. The Social Determinants of Health Commission and resulting report (Marmot et al., 2008) noted that factors within the social environment and related lifestyles are as important, if not more so, than direct healthcare and treatment of diseases to ensuring the wellbeing of individuals everywhere in the world.

Three other related additional concerns with regards to the focus of current dominant discourses in health policy circles include the following:

- 1 The continued existence of policy ‘silos’: There are a few examples of health and social care agencies talking together and sometimes – over nationally important health issues – discussion and action with subsequent agreement from multiple government ministries. However, for the most part, health and other policy arenas (e.g. industrial policy, finance policy, education policy) are ‘siloesd’ and rarely try to ensure that their

goals are matched or that issues are approached from a holistic view. This is often matched at the practice level by a lack of discussion and action across traditional disciplinary boundaries (e.g. between social workers, doctors, nurses, housing officers, teachers etc.) which further exacerbates the silos.

- 2 The need for a broader approach to strengthening of national health systems: Early efforts to strengthen national health systems through Sector Wide Approaches (SWAs) were challenged in the late 1990s and early 2000s by the re-emergence of emphasis on so-called ‘vertical programmes’ to tackle specific diseases, notably HIV/AIDS, TB or malaria. Realising the problems related to the vertical approaches there has, in recent years, been a growing emphasis on health systems strengthening and the need to ensure that all projects and programmes fit within national health system priorities and requirements. However, more could still be done to apply a wider lens that focuses on more than simply *healthcare* systems.
- 3 The increased emphasis on results-based-management: The extent to which the above two issues have arisen is linked to the form and content of evidence based policy discussions and the resulting type and form of measurement of health systems and government performance that is undertaken. In some cases, this has led to an excessive focus on documenting and measuring results at the expense of ensuring direct attention to users in the healthcare system.

As a result of the above, a range of different perspectives can be observed that dominate health policy discussions at national, and particularly global,

levels. These fit within one of two overarching approaches outlined in the first or second column in Table 1 below.

Table 1 Health policy discussions and development: from two overarching opposing approaches to an integrative approach

Health as a means to economic growth	Health as a means to achieve social development and reduction of inequality	→	Health as an integrated element of and contributing factor to economic and social development built on equity and inclusion
Health as absence of disease	Health as wellbeing	→	Health as wellbeing
Firms and private sector as drivers	Role of other actors, especially state	→	Complex network of actors
Supply driven	Demand driven	→	Problem driven
Knowledge as science, technology and innovation (STI)	Knowledge as doing, using and interacting (DUI)	→	Multiple flows of knowledge and power (STI and DUI)
Health innovation as new products	Social innovation is key	→	Multiple types of innovation and combinations of innovations required

Source: Authors

On one side, you have those that see the goal of development as economic growth, place an emphasis on a narrow definition of health and regard the private sector as the key driver in healthcare delivery and management. In this overarching approach the market for health and healthcare is dominated by the supply side and solutions focus on science and technological innovations (STI) solutions; particularly the introduction of tangible products.

In the converse approach, development goals are defined much more broadly in terms of wellbeing with a larger role to be played by the state and the end user of healthcare as the market is dominated by the demand side. Within such an approach, knowledge requirements are also defined more broadly with an emphasis placed on doing, using and interacting (DUI) leading to a focus on social innovations.

These two overarching approaches are at either end of a spectrum of perspectives. As such, the majority of perspectives that are presented in academic and policy literature fall somewhere between these two approaches. That said, debates are often discussed as being polarised across one or more of these divides (Mackintosh and Mugwagwa, 2014; Cassiolato and Soares, 2015). Table 1 provides, in columns 1 and 2, useful 'ideal types' for use as focusing devices for the various different arguments that are shared around the world against which an alternative juxtaposition can be made.

This report will argue that an alternative juxtaposition is needed; an approach that is more integrative and which is outlined in column 3 of Table 1.

Such an approach sees the role of development as being to meet both economic and social development in order to support equity and inclusion. As such, the definition of health emphasises wellbeing. This approach recognises a complexity of actors involved in designing, delivering and monitoring health and wellbeing activity. As such, the approach stresses the importance of a problem based focus to market driven solutions, utilising multiple flows of knowledge and innovation within the context of multiple positive and negative power flows.

Specifically, work from within the Globelics community (and more generally from within the Innovation Studies and Science and Technology Studies fields) over the past 10 years has highlighted the usefulness of thinking in terms of 'health innovation systems', learning and competence building systems, to address these disconnects. Such work has focused on, but is not limited to:

- 1 Thinking and conceptualising health and innovation systemically and in a wider perspective as to who are the actors, and in what spheres does health policy and healthcare take place both in the immediate vicinity of the hospital or clinic but also much more broadly in society and throughout the value chain(s)
- 2 Reviewing the role of partnerships and networks of actors in the development of research capacity related to health and health innovation systems
- 3 Considering the implications of new technologies – ICT, biotechnology, nanotechnology, synthetic biology – on the future of healthcare and

health systems, particularly in relation to low and middle income economies

- 4 Investigating the viability and opportunities of local pharmaceutical production including issues of finance and human resources
- 5 Researching issues of intellectual property rights (IPRs), trade relations and governance on local and international pharmaceutical production and research including South-South collaboration local, regional and international.

This report will review current work in these areas and others to provide the latest thinking on how health and development can benefit from thinking from within innovation related perspectives. Investigating health systems through an innovation and development studies lens – in terms of health innovation systems – provides an alternative way of considering the underlying requirements for successful innovation throughout a health system. In this way, it provides a new set of insights into how health systems, especially in low income settings, might be more effectively strengthened so that they can provide high quality healthcare that is accessible to all and promotion of healthy livelihoods more generally.

The Globelics Thematic Report and Series

This report therefore asks readers to rethink the role of innovation in health systems strengthening in two ways. First, by taking a wider definition of what is meant by the terms ‘health’ and ‘innovation’. Second, by providing an alternative

integrative policy lens through which to develop plans for the strengthening of health systems at a country level. This alternative lens sees social innovation as the cement that binds the building blocks of health systems strengthening together and not simply as a sub-set of one of the building blocks. In so doing, it aims to reignite the debate on the role of innovation and particularly its role as a mechanism for building stronger and more sustainable health systems.

It is able to do this by drawing on the work of academic scholars from around the world working in the field of innovation and development. These make up members of the Globelics community who have been working to advance academic thinking and policy analysis of the linkages between innovative activity and economic and social development since the early 1990s.

This report is one of a series of Globelics Thematic Review reports prepared during the period 2011 to 2016. Each report, and a set of related dissemination activities, focuses on a specific issue of interest and aims to communicate insights from the Globelics community to a wider audience, forwarding these into wider policy circles and overseas development assistance organisations. The Globelics Thematic Reviews constitute a commitment made to the Swedish International Development Corporation (Sida) in connection with a 2011 grant for the Globelics Secretariat located at Aalborg University. The reviews give an overview of research outcomes related to a particular topic as well as reflections on policy implications. Previous reports have focused

on: innovation and development, innovation for low carbon energy development, and innovation for natural resource management.

Methodology

This report has been developed through a comprehensive desk review of current literature on health innovation research from within the global health field as well as from within the innovation studies field, especially the Globelics community. It has also benefitted from a consultative process with members of the Globelics community and those from outside the community providing comments and feedback on the report's ideas and drafts of the report. The report was in development over a 16-month period from March 2015 to July 2016. Further details of the methodology are outlined in Annex 1.

Report format

The report starts in Chapter 2 with an outline of different ways of thinking about health, health systems and health systems strengthening. The Chapter outlines the importance of:

- 1 Thinking about health as more than absence of disease
- 2 Considering issues of equity and wellbeing
- 3 Focussing on health systems strengthening but moving beyond a simple focus on more efficient healthcare solutions to a wider focus on more efficient wellbeing and livelihood solutions.

In Chapter 3, the report moves on to ways of re-thinking health innovation. It discusses some of the latest work on technological innovations but also introduces examples of social innovations related to health and wellbeing for all. These social innovations include process or intra-organisational innovations, inter-organisational innovations, institutional innovations and systems level innovations in healthcare. It introduces the idea of health innovation systems; the idea that successful technological and social innovation for better health requires a supportive enabling environment. Specifically, it argues that:

- 4 For the promotion of improved wellbeing and sustainable livelihoods there is a need for systems level changes
- 5 This requires social innovation in multiple spheres, not just technological innovation
- 6 Social innovation creates, and is key to creating, the learning and competence building that enables a system to adapt and change to new circumstances
- 7 One approach to recognising the importance of social innovation for technological product innovation has been the promotion of the concept of 'health innovation systems'

Chapter 4 introduces an integrative analytical lens for analysing policies for health and wellbeing systems strengthening. Specifically, the lens recommends looking at the whole system and the way

to ensure all elements of the system are included, while juggling multiple knowledge, power and politics flows. The lens provides an opportunity, at a very high level, to consider deficiencies in a national health system in order to know where to focus more attention in order to strengthen the system into a health and wellbeing system where innovation is endemic. In turn, this should help movement away from policy silos that often occur and create more effective health systems able to secure health and wellbeing for all. Reviewing two situational cases of health problems from India and Kenya, the framework highlights:

- 8 That the building blocks of the health system need ‘cement’ to bind them together; social innovation provides this ‘cement’ through the creation of system building competences
- 9 That knowledge (and politics) flows as determinants of systems strengthening are centrally important
- 10 The importance of active government and regulatory support for systems strengthening to ensure a facilitatory enabling environment

whereby knowledge flows are promoted and politics flows become positive rather than negative in nature

- 11 Such an approach moves away from ideas of ‘healthcare systems’ to the idea of ‘innovative health and wellbeing systems’ for sustainable economic and social development’

The final Chapter, Chapter 5, provides a short conclusion to the report, recapping the key points. It outlines the arguments of the report that social innovation is as central, if not more so, as technological product innovation for the future of health and wellbeing systems strengthening. It argues that there is a need for changes within the policy process to effectively encourage greater levels of social innovation. Outlining various deliberations for policy makers, the Chapter reflects on these in the context of ideas on the future prospects for health systems in low and middle income countries and provides recommendations on how to move discussions and action forward through new research and collaborations that create opportunities for learning cultures in the research and policy spheres as well.



2. Rethinking health and health systems

Key points

- 1 We need to think about health as more than absence of disease
- 2 This includes placing an importance on issues of equity and wellbeing
- 3 In view of this wider approach, the concept of health systems strengthening is important but must move beyond a simple focus on more efficient healthcare solutions to a wider focus on more efficient wellbeing and livelihood solutions.

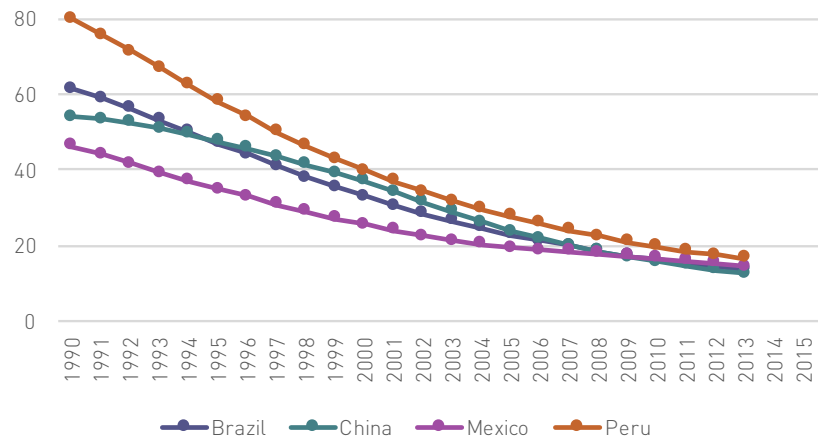
As the world moves towards meeting the Sustainable Development Goal (SDG) 3 related to health, it is useful to start by taking stock of the world's health and progress towards the provision of health for all. The previous Millennium Development Goals (MDGs) gave countries an earlier focusing device on which to measure, amongst other things, a country's progress towards achieving a healthier population. The results of efforts to meet the health MDGs have been substantial

but have not always met the targets set. Child mortality (MDG4) dropped by over 50% in absolute global terms from 1990 to 2015 (although the original target of a two-thirds reduction was not met). Global maternal mortality (MDG5) dropped by nearly half (but again did not meet its two-thirds reduction target). The target on HIV/AIDS (MDG6) was not met although access to antiviral treatment increased by over 50%.

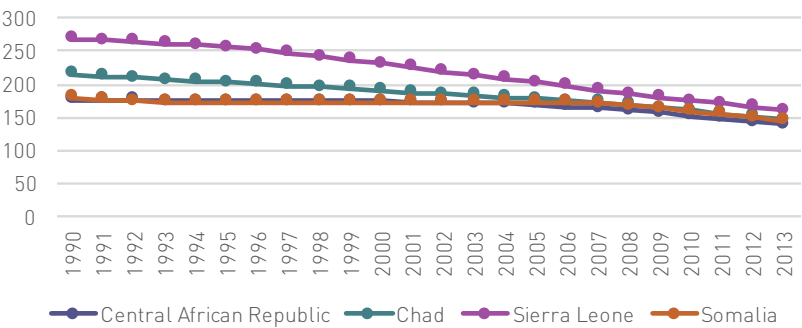
However, while being useful measuring devices on a global scale, these high-level figures miss out the nuances at national level. When you consider country level results, many African countries missed their targets for child and maternal mortality. Many countries in Asia and Latin America did much better. Unfortunately, virtually no regions of the world did well with regards to MDG6 (CDG, 2015). Figure 1 outlines the status of some of the best and worst performing countries identified by WHO in 2012 as 'Countdown countries' or those that were unlikely to meet health related MDGs 4 and 5 with regards to maternal and child health.

Figure 1 Data for four of the best and worst performing countdown countries with regards to MDGs 4 and 5

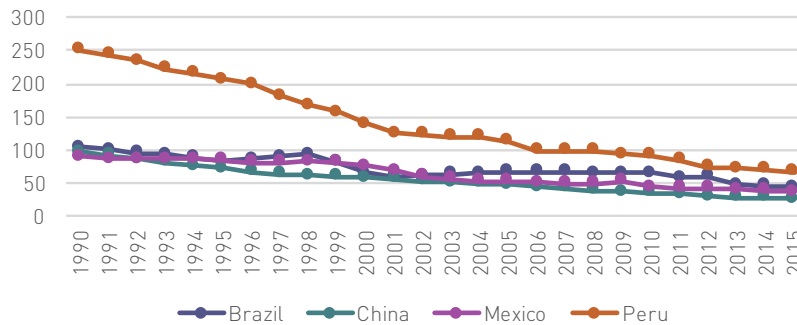
**MDG4 Under 5 mortality rate per 1,000 live births (1990 - 2013)
for 4 of the top performing 'countdown countries'**



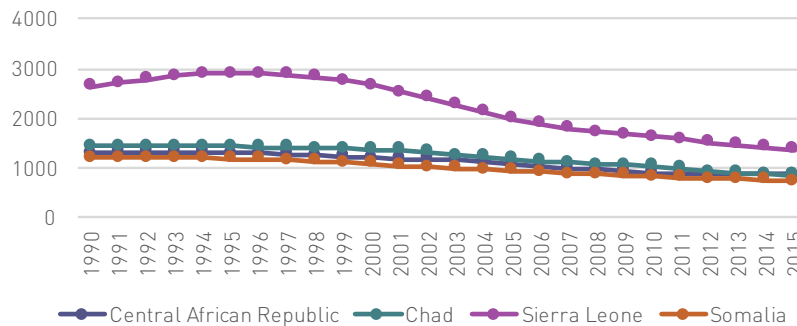
**MDG4 Under 5 mortality rate per 1,000 live births (1990 - 2013)
for 4 of the worst performing 'countdown countries'**



MDG5 Maternal mortality ratio per 100,000 live births (1990 - 2015) for 4 of the top performing 'countdown countries'



MDG5 Maternal mortality ratio per 100,000 births (1990 - 2015) for 4 of the worst performing 'countdown countries'



Source: <http://mdgs.un.org/unsd/mdg/Data.aspx> (accessed 07/08/16)

While the MDGs provided a way of measuring progress globally, regionally and nationally towards improving the status of population health, they only focused on a few areas of health. Critics argued that they did not include non-communicable diseases (Seffrin, 2009), mental health (Miranda and Patel, 2007) or disabilities (Wolbring, 2011). Others have commented on the fact that they did not include a focus on the underlying strength of health systems (Haines & Cassels, 2004; Keyzer & Van Wesenbeeck, 2006).¹

The SDGs have been developed to be more inclusive in nature. While there is only one overall SDG for health (SDG 3: Ensure healthy lives and promote wellbeing for all at all ages), the proposed indicators to measure progress against this goal are much broader than those set for MDGs 4, 5 and 6. As such, the indicators include a wider range of diseases, road traffic accidents, mental health and substance abuse. SDG3 also includes indicators relating to access to healthcare services, training of healthcare workers and early warning systems.

The inclusion of these latter health systems-related issues are important because the SDGs will only be met if there is more investment, more uptake and more systems strengthening. The Global Health 2035 modelling scenario found that if low and middle income countries increased their financial investment in health – with help from others

through donor assistance – it would be possible to see a ‘grand convergence’ of health outcomes whereby the disparities between the health outcomes of the rich and poor nations of the world are significantly reduced (Jamison et al, 2013). The largest cost requirement in the scaling up of health-care is in the area of health systems strengthening. A 2015 report estimated the cost of scaling up health-care using a range of scenarios, with and without investment in additional research and development (R&D) for new technologies. They found that for low income countries:

“HSS [Health system strengthening] is the biggest driver of overall incremental costs, comprising more than 70% of costs in 2015 and falling to 56% in 2030. Of these HSS costs, the dominant component is infrastructure, including equipment and vehicles. An important outcome from such investments is that it leads to a *functional health system platform for service delivery* that can tackle other long-term health challenges, not just infections and RM-NCH [Reproductive, maternal, neonatal and child health] conditions. The cost of scaling up the new health interventions generated by investments in R&D is estimated at an additional incremental cost of \$2.5-\$3.5B per year for low income economies, or about 10–15% of the total cost, depending on the year.... From a cost-benefit standpoint, the projected enhanced

1 For a good review of the limitations of the MDGs, see Fehling et al. (2013) which outlines a review of academic papers critiquing the MDGs up to 2013.

investment scenario with R&D would represent a highly attractive investment. The cost per death averted in this scenario starts at US\$11,600 in 2015 (the time of maximum investment in HSS and before the interventions are fully scaled up) and declines to US\$4,300 by 2030.” (Boyle et al., 2015:10; italics in original)

But many countries have a long way to go. The worst performing countries in Figure 1 have governments that are challenged by a range of factors (from on-going war and political uncertainty to poor education and training systems to large population sizes) that mean small financial investment in health when measured as a per capita amount. The result is that these countries suffer from chronic shortages of well trained staff and inadequate health facilities. Table 2 (next page) provides a comparison of their situation as opposed to that of the top performing countries using a few indicative indicators of health systems performance. This is not to say that the four countries representing the top performers in the countdown countries do not have issues of their own; they were identified as part of a group of 75 countries least likely to meet the MDGs 4 and 5 by the Countdown to 2015 project. In fact, when you compare them to the situation in the UK, which topped a recent Commonwealth Fund report comparing health systems (Davis et al., 2014), or with France, which came top in the WHO 2000 World Health Report that was the

first to rank health systems, the differences in health systems becomes very stark indeed.

The idea that health systems strengthening was an important element in achieving improved health outcomes was publically proposed at a global health policy level in the early 2000s, especially with the publication of the WHO’s World Health Report in the year 2000. Since then debates about what constitutes a ‘health system’ and how it is possible to ‘strengthen’ a health system have gathered pace. One starting point for these debates is differing approaches to the definition of health.

Definitions of health

In 1948, the WHO defined health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 2006). Despite this, many would argue that there has been a tendency at various times, between 1948 and today, to focus on the latter part of the definition with good health equating to the absence of disease and infirmity only. Some argue this is because of a historical mind-set that commodifies every aspect of life where “the institutionalised mainstream health system is portrayed as products and services emanating from the operations of a global medical industry which is becoming increasingly *financialised*” (Maharajh, 2015: 60; his emphasis). Others argue it is more an issue of ease; that it is easier to tackle disease and physical illness, especially within resource-constrained settings. A major example of these different approaches to defining health occurred in the global health policy

Table 2 Health systems performance by indicative indicators for selected countries (latest figures available)

	Health expenditure per capita, current US\$	Hospital beds per 1,000 people	Nurses and midwives per 1,000 people	Physicians per 1,000 people
UK	3,685	2.9	8.8	2.8
France	4,955	6.4	9.3	3.2
Selected top performing countdown countries				
Brazil	947	2.3	7.6	1.9
China	375	3.8	1.9	1.9
Peru	347	1.5	1.5	1.1
Mexico	674	1.5	2.5	2.1
Selected worst performing countdown countries				
Central African Republic	13	1	0.3	0.0
Chad	34	No data	0.2	0.0
Sierra Leone	92	0.4	0.2	0.0

Source: World Bank database/ world development indicators; <http://databank.worldbank.org/> (accessed 07/08/16). All data for years post 2010, other than nurse/midwife/ physician data for CAR (2009) and Chad (2006) and hospital beds in Sierra Leone (2006). Somalia has been removed because there is no data for any of these indicators for the past 10 years available.

field in the 1970s and 1980s. International policy swung between that which focused on promoting ‘selective biomedical interventions’ (programmes to reduce specific high-burden diseases) to that which focused on more comprehensive healthcare solutions (focusing on strengthening a wider set of healthcare services).

The pendulum of this argument since the early 2000s has increasingly swung again in favour of wider definitions of health and the importance of universal healthcare coverage. The first signs of this are often linked to the WHO’s Commission on Social Determinants of Health which ran from 2005 to 2008, although the debate was already present in the 1990s (c.f. Marmot and Wilkinson, 1999). The work on social determinants of health emphasised the inability of healthcare provision around the world to focus on wider issues beyond the treatment of disease. The approach emphasises the importance of thinking about a much wider set of social and economic factors that influence health and wellbeing. The social determinants of health are defined as “the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems.” (WHO, 2016a)

This discussion on social determinants is allied to a debate that started much earlier with critiques of the 1993 World Development Report (c.f. Anand and Hanson, 1997 and 1998). This is a debate on

equity and inequality in health and, allied to this, a wider debate on the role of social justice in, and for, health. There are significant discussions as to the best way to regard equity and equality in health from the work of Whitehead, 1992, to Culyer and Wagstaff, 1993 through to Braveman and Gruskin, 2003, Marmot et al, 2008 and a special issue of the American Journal of Bioethics (Preda and Voigt, 2015). Essentially, this debate questions whether health inequalities can be summed up as referring to differences in health while health inequities are differences in health that are unjust and unfair.

The result of these various different debates is that in 2008 and 2009 a discussion took place in the British Medical Journal on the subject of how health is defined. It led to the development of an alternative definition to that agreed by the WHO in 1948. The alternative definition defines health as “the ability to adapt and self-manage” in the face of social, physical, and emotional challenges (Jadad and O’Grady, 2008).

Furthermore, efforts since 2012 to get more countries to provide universal health coverage are seen as a means of addressing health inequities, health inequalities, and social inequalities in health (Reid, 2015). The idea of universal health coverage fits with the wider agenda of the WHO of ‘Health for All’ and is the idea that “all people obtain the health services they need without suffering financial hardship when paying for them” (WHO, 2016b). The ‘call to arms’ for universal health coverage has led to an increasing emphasis being placed on the development or revival of social insurance systems

across the world from the USA through Kenya to Vietnam as a pillar of a functioning health system.

Health systems

The World Health Report 2000 signalled a new era in global health debates. For the first time, it attempted to rank countries based on their health systems performance in reducing disability adjusted life years. While the ranking system itself was highly controversial, the discussion it opened relating to the definition of a health system and components required to strengthen it has proved popular (McKee, 2010). The result has been an increased interest for the last 15 years on health systems strengthening within global health discussions and, increasingly, also at the level of national government around the world.²

There is no one single definition of what a 'health system' is (Atun, 2012). It may be argued to be a 'means to an end' or a system which 'exists and evolves to serve societal needs' with 'components' that "...can be utilized as policy instruments to alter the outcomes" (Hsiao, 2003; cited in Atun, 2012). A health system has also been described as 'all the activities whose primary purpose is to pro-

mote, restore or maintain health.' (WHO, 2000: p.5). These definitions take into account not only the healthcare elements of a health system, i.e. the treatment of disease and illness. They also take into account the wider definition of health as a state of complete physical, mental and social well-being.

The components of a functioning health system, as initially laid out in the World Health Report 2000, have become widely used in global health but also, more importantly, in national level discussions over the past 10 years. The components of the health system outlined were: service provision, resource generation, financing and stewardship (WHO, 2000). Policy makers and others have since refined the definition and expanded to six 'building blocks' of a health system. These are outlined in Figure 2 and include: leadership and governance; healthcare financing; health workforce; medical products and technologies or access to medicine; information and research or health information systems; and service delivery (WHO, 2007; WHO, 2015).³

2 We would argue that this development was sparked off by the recognition in the early 1990s (Gilson and Raphaely, 2008) of the need for more critical health policy analyses focusing on the context in which health policy was developed and implemented, bringing in the issues of politics, process and power (Walt, 1994).

3 There are others that have been put forward by the World Bank, Reich and others (see Shakarishvili et al., 2010 and WHO, 2010) but the term building blocks and these six elements are frequently referred to in the global health literature and have become a starting point for a sector-wide monitoring framework on health systems performance (WHO, 2010).

Figure 2 WHO's health system framework



Source: http://www.wpro.who.int/health_services/health_systems_framework/en/; (accessed 07/03/16)

Health systems strengthening

Just as the term 'health systems' is hard to pin down, so too is the concept of 'health systems strengthening' (Shakarishvili et al., 2010). Shakarishvili et al. (2010) define health systems strengthening in terms of interventions that are conducted to enhance one of the health system's 'components' or building blocks (for example, capacity building, data collection or organisational reforms). Frenk (2010) takes a systems based approach to the discussions and sees four elements to health systems strengthening, rememberable through the abbreviation LIST: leadership, institutions, systems building and technologies. Such a definition is couched in terms of the six building blocks earlier presented for health systems but emphasises, in greater depth, the importance of the interconnections, power and politics that make up a system – taking a set of disparate actors from simply working together to functioning for the benefit of a wider goal; a greater whole. Such a notion of systems and the interconnections between actors has become increasingly important within the global health community discussions in recent years and therefore we will return to this later in the Chapter.

For now, it is important to mention two things with regards to this wider definition of health systems. First, such a recognition of the complexity of actors in the system is important. Systems are organic and determined by the actions of the actors and institutions involved and the power and politics flows that result. This is illustrated by any num-

ber of public debates regarding how best to fund healthcare with limited resources. For example, the long standing overarching debates on comprehensive as opposed to selective healthcare were part of a much wider political debate taking place at the time (Lawn et al., 2008). In another example, the more recent discussion on whether to focus health spending on very expensive individualised drugs to tackle the rise of non-communicable diseases (especially cancers) or tried and tested alternatives is influenced by various industry actors and patient groups (c.f. different arguments by Savard, 2013; Hedgecoe, 2004; Needham, 2014).

Second, all of this has taken place within a context of controversy as a result of the debate as to whether health systems strengthening is still too narrow in its focus and dominated by technical solutions rather than systemic approaches that focus on more holistic efforts. These debates have been vocally played out in the debate regarding the role of global health initiatives (Hafner & Shiffman, 2013; Marchal, Cavalli, & Kegels, 2009; Storeng, 2014) but also rage in the research arena on health systems strengthening (Adam et al., 2012a; Frenk, 2010).

The World Health Report 2000 also coincided with the introduction of the MDGs. These goals provided the world with a policy-focusing device (Verspagen, 2013) for international, national and local actions taken to address the multiple issues affecting the world. High on this list were a set of global health issues, namely child mortality, maternal mortality and the morbidity and mortality

caused by three 'big' diseases: HIV/AIDS, Malaria and Tuberculosis. These health related goals focus heavily on reduction of disease burden, particularly in low and middle income countries (*vis a vis* countries of the so-called 'global North'). This inequality between the health prospects for populations in different countries was a major reason for the World Health Report's focus on health systems performance in 2000 (McKee, 2010).

These differences remain fifteen years later and provide a continually valid reason for the continued focus on health systems strengthening. Over the last 15 years, the focus on health systems strengthening has continued to gain ground because of continued concerns over the lack of capacity within low and middle income countries (and at times even countries in the global North) to manage their health systems. The issue of management or 'governance and leadership' to use the building block terminology (or 'stewardship' to use the World Health Report of 2000 definition and that of Saltman and Ferroussier-Davis (2000)) is the major issue that needs resolving. It is also one on which all authors appear to agree; without good leadership and governance, the rest of the blocks will fail to stand up strong. These discussions tend to focus on the importance of leadership at a national level. However, governance issues are important at a global level, too. The debate (c.f. Clift, 2014) on the effectiveness of the WHO to fulfil its mandate to act as "the directing and coordinating authority on international health work" (WHO, 2013) is one such example. So too are debates on the power of global health actors,

be they the various Global Health Initiatives, new donors on the scene such as the Gates Foundation, or the increasing power of some newly innovative countries (see below).

The debates on the actors within the system and their influence is one of a number of debates that add nuance to the discussions on health systems strengthening. Another important debate is that relating to how international development assistance more generally is provided to low and middle income countries. The final relevant debate to mention here is that relating to the way the impact of health interventions and health systems strengthening are measured. These debates (outlined below) have influenced the way health systems function on the ground in different countries and therefore determine the extent to which these systems have been able to strengthen or build up the relevant capacities and capabilities to provide accessible and affordable healthcare to the whole population.

Who governs the global health arena?

The mid 1990s saw the rise of a new set of actors on the global health scene with the rise of innovative partnerships to develop or improve access to new or improved drugs, vaccines or diagnostics. These started small but have since become dominant players on the global health arena providing the majority of funding for global health research, rivalling the US National Institutes of Health (Moran et al., 2010). The biggest of these, known as **Global Health Initiatives** (World Health Organization Maximizing Positive Synergies Collaborative Group, 2009) include the Global Fund for AIDS, TB and Malaria and the Gavi Alliance. Both of these work with governments and the private sector to stimulate the manufacture and supply of new or improved vaccines, drugs or diagnostics and, in more recent years, also their successful introduction into health systems at country level.

These new organisational forms have transformed not only the global resource flows for health but also the wider governance of global health, changing the balance of power at the global health policy level (Rushton and Williams, 2011) determining what countries and other actors in the health system globally and nationally focus attention on. This relates back to the debates on the role and power balance between the WHO; the GHIs and new donors, especially the **Bill and Melinda Gates Foundation** (Martens and Seitz, 2016).

Global Health Initiatives and the Gates Foundation are, however, not the only influences to change the landscape of global health governance in recent years. Increasingly important is the rise of a group of '**innovative developing countries**' or IDCs (Morel et al, 2005a). These are a set of countries including India, China, South Africa, Brazil, that have disrupted the traditional innovation paths within the global pharmaceutical industry (Hwang and Christensen, 2008). These countries have become leading producers of low-cost, high volumes of generic drugs that challenge the dominance of the leading pharmaceutical manufacturers in Europe and the US.

How should development assistance be provided?

The second area of debate to introduce here is related to the issue of international development assistance and its impact on health spending at national level. Development assistance for health (DAH) has been steadily rising peaking at US\$ 38 billion in 2013; in 2015 the figure was US\$ 36.4 billion (Dieleman et al., 2016). DAH, the provision of financial and in-kind support through development assistance channels (Moon and Omole, 2013), is predominately provided by governments, the US government providing nearly 35% (Dieleman et al., 2016). The majority of DAH is focused on single issues (HIV/AIDS, maternal and child health getting the lions share), while support for health systems strengthening receives very little; just 7.3% of total DAH in 2015 (Dieleman et al., 2016). This support for health systems strengthening has increasingly been focused on encouraging more coordination across departments through a focus on 'sector wide approach programmes' and 'basket funding'. Some donors are also increasingly providing this as general budget support; allowing national governments to decide how best to spend the money. However, in all cases there is an increasing focus – demand even – that money is spent in priority areas (see debate 3 below) and through increasingly coordinated systems whether at national government level or within the UN system (i.e. the UN ONE initiative aims to have all activity going through one organisation – one leader, one fund, one budget, one programme etc.) (Moon and Omole, 2013).

How can policy lead to better impact?

In the late 1990s, the TEHIP project monitored health needs of two districts in Tanzania and fed the results into healthcare planning to ensure resources were disbursed to the essential interventions. The project also analysed the effectiveness of this evidence based policy approach to healthcare planning. The project was a resounding success showing massive improvement in health outcomes – child mortality fell by 40% in the two districts over the 5 years in which the project was implemented (ODI, n.d.).

Evidence based policy (EBP) gained ground partly as a result of the World Development Report 1993 entitled ‘Investing in Health’. This World Bank report argued that: “given the scarcity of available resources for health, especially in low income countries, the planning for and setting of priorities for essential health interventions should be based on burden of disease and cost-effectiveness analysis. The analysis of health systems showed that many low and middle income countries misallocate these scarce health resources toward cost-effective interventions, coupled with inefficiencies in planning and highly centralized decision-making.” (Neilson and Smutylo, 2004: p.12)

The call for more effective use of resources is a sensible one but the EBP movement has been called into question (Black and Donald, 2001) for its linear focus on the relationship between evidence, policy and impact. That said, the recent popularity of the ‘randomistas’ (Ravallion, 2009) and debates about research impact (c.f. Mendez, 2012; Davis et al., 2003; Lavis et al., 2005) shows that this approach is far from having been forgotten about and argues that it does have its benefits (Bosch-Capblanch et al., 2012). One reason for this is perhaps the increasingly scarce financial resources being put into global health issues, following the latest financial crisis. There are increasing calls for greater discussions with regards to ‘value for money’ (c.f. Glassman et al., 2013). Such arguments also feed into wider and older discussions on stewardship of health systems and discussions around the rise of new public management strategies in healthcare situations (Ferlie, 1996). The increased focus on results has – in some countries – led to an excessive focus on documentation and monitoring (Dahler-Larsen, 2012) and criticism that all the efforts to collect data and document actions in health systems and related ‘care’ systems, e.g. for the elderly, takes away time and energy from direct interaction with those needing care and attention.

The rise of health systems and policy research

As outlined above, since the World Health Report of 2000 there has been an increasing emphasis placed on social science research as well as biomedical research for health systems strengthening. Specifically, there has been an increasing emphasis within global health discussions on the need for more research on health systems, health policy and implementation science. There are several journals now dedicated to this type of research starting with the early establishment in 1996 of the Journal of Health Services Research and Policy, the BioMed Central Journal of Health Services Research which includes a section dedicated to health systems of low and middle income countries (from 2000) and Health Research Policy and Systems (since 2003).

There has been an increasing emphasis – alongside the growing awareness for prevention approaches and institutional and organisational change in research – on the implementation of healthcare and health policy (Hales et al., 2016). In addition, there has been an increasing focus on research into the functioning and strengthening of health systems. This includes discussions on what comprises a health system, aimed at understanding the importance of not just each building block but how they fit together and affect each other; often taking a complex adaptive systems approach (see for example Adam and de Savigny, 2012). This work has been championed by the Alliance for Health Systems and Policy Research as well as COHRED through their annual meetings and re-

ports.⁴ Perhaps the biggest sign of this change has been the World Health Report 2013 that focused on the role of health research for universal health coverage and specifically the need to strengthen national health research systems.

Health Policy Research Systems are argued to be research that:

”seeks to understand and improve how societies organize themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes. By nature, it is interdisciplinary, a blend of economics, sociology, anthropology, political science, public health and epidemiology that together draw a comprehensive picture of how health systems respond and adapt to health policies, and how health policies can shape – and be shaped by – health systems and the broader determinants of health.” (Alliance for Health Policy and Systems Research, 2011; cited in Gilson, 2012: p21.)

Gilson (2012: p. 21) argues that it is

“a multidisciplinary research field, distinguished by the issues and questions addressed through the research rather than

⁴ See <http://www.who.int/alliance-hpsr/en/> and www.cohred.org

by a particular disciplinary base or set of methods” and that it: “includes research that focuses on health services as well as on the promotion of health in general; includes concern for global and international issues as well as national and sub-national issues, as global forces and agencies have important influences over health systems in low and middle income countries; encompasses research on or of policy, which means that it is concerned with how policies are developed and implemented and the influence that policy actors have over policy outcomes – it addresses the politics of health systems and health system strengthening; promotes work that explicitly seeks to influence policy, that is, research for policy.”

As such, Gilson (2012: p30) goes on to point out that it is research that occurs at the intersection of health systems and health policy being concerned with system functioning and policy change. It therefore is more than just research on health systems or on health policy. It is concerned with all building blocks within the health system and not just the health service delivery building block. As a result, it can be differentiated from implementation research or operations research.

At the heart of health systems and policy research is an understanding of the health system – what it is and how it works. In the last 10 years, this research has been heavily influenced by sys-

tems thinking and particularly complex adaptive systems thinking (de Savigny and Adam, 2009). Systems thinking places an emphasis on the interactions and connections between the different actors that make up a ‘system’. Complex adaptive systems thinking can be described as a system that adapts and evolves through self-organisation of a complex set of interconnected parts (de Savigny and Adam, 2009).

While it is often difficult to boundary a system, the idea of using systems thinking is that it helps to move beyond the linear approach or even the circular approach of research to policy to implementation to evaluation/further research etc. It introduces the importance of feedback loops and contexts that make the process ‘messy’. In this way, despite the fact that it could be argued that the field received a boost from the rise of evidence based policy (EBP), this field of research is at odds with the linear models of the policy process put forward by the EBP literature. It is perhaps no surprise, then, that many of the writers who critiqued the dominant approach to studying health policy and utilised more non-linear policy process approaches (notably Gill Walt and Lucy Gilson) have become some of the core researchers within the health systems and policy analysis literature.

It is worth noting that, up to this point, we have been referring to health systems and policy research very generally, although implicitly with a focus on research targeted to low and middle income countries. This field of research is, however, divided into research focused on the global North and that

focused on low and middle income countries. A review of the literature on ‘health innovation’ conducted for this report revealed that the majority of papers from within the health journals reviewed were focused on the healthcare systems in the global North, specifically the UK, US and to a lesser extent Scandinavian countries (see Chapter 3).

Interestingly, these papers focused on innovation in healthcare delivery or healthcare services more than innovation for health systems strengthening, implicitly or explicitly, while the papers from low and middle income countries focussed more on issues related to health systems strengthening. This might have to do with two trends. First, the dominant role in the Global South of global health programmes which – especially in their early years of existence – tended to bypass and even undermine national health systems rather than strengthen these. Second, health systems in the Global North have for a period of time been seen as more well-functioning than those in the low and middle income countries. This situation is now potentially changing due to the new challenges that national health systems in the Global North are facing (e.g. caused by people living longer, access to new and very expensive medicines etc.).

Perspectives from innovation studies on health and health systems

The innovation systems literature came out of discussions taking place with regards to the uneven development of countries around the world and the idea that different innovation capacities could

be an explanatory factor for inequities and inequalities. Hence, at the heart of these discussions has always been a focus on issues of equity and equality or rather the need to understand why there is inequality and inequity in the world and to provide solutions to reduce these.

While initially focused on issues relating to economic development more generally, the perspective has increasingly considered specific development challenges such as health, education and housing (Cassiolato and Soares, 2015). This shift in emphasis in part reflects wider development debates, which during the 1970s and 1980s focused on poverty as measured in economic terms (often Gross Domestic Product (GDP) per capita). Since then, broader interpretations of poverty as lack of possibilities, voice etc. as advocated by United Nations Development Programme (UNDP) and other UN agencies have been promoted and even picked up by the World Bank (one of the original promoters of defining poverty in economic terms).

This also relates to discussions within the international development policy community with regards to inclusion and development. Since the late 2000s, there has been an increasing emphasis within the donor and multilateral community on the idea of ‘inclusive development’. This is defined in terms of what it is not, thus:

“Starting with growth, which has a tight and well accepted definition as an increase in real per capita income, pro-poor growth is identified as that which also reduces

income poverty. Inclusive growth is that which is accompanied by lower income inequality, so that the increment of income accrues disproportionately to those with lower incomes. With these definitions, growth can be pro-poor without being inclusive, since (as happened in many countries over the past two decades) growth can be accompanied by falling poverty but rising inequality. The concept of development differs from growth in expanding the focus from income alone to other dimensions of well being, in particular education and health. Inclusive development thus refers to the improvement of the distribution of well being along these dimensions at the same time as the average achievement improves. The MDGs identify a number of these dimensions, and provide a good framework for measuring and identifying inclusive development.” (Kanbur and Rauniyar, 2009)

This is an important set of discussions because it furthers the debates about the relationship between health and economic development. Specifically, the notion of inclusive innovation brings in issues of inequality and inequity that are often missing from discussions on economic development. It also highlights the need to consider the overlap between policy discussions, notably health or social policy and economics-related policies of trade, finance, innovation etc.

Since the first discussions on the relationship between innovation and economic growth, scholars in the field have been asking questions regarding the nature and purpose of economic growth, the forms of economic growth and increasingly whether that growth is inclusive. This fits with wider debates that are taking place within international development around inclusive development, inclusive growth and pro-poor growth within the World Bank, OECD/bilateral agencies and the UN system. Such discussions have realised the need to move beyond technological innovation in formal science institutions and also consider innovation elsewhere (Utz and Dahlman, 2007).

However, much of these policy discussions are still rhetoric and therefore a range of writers, notably from within the Globelics community, have spent time academically critiquing current debates in this area. These scholars (Cozzens and Kaplinsky, 2009; Lorentzen, J. and Mohamed, 2009; Arocena and Sutz, 2012; Papaioannou, 2014; Foster and Heeks, 2013) argue for much deeper analysis of the relationship between innovation, inequality and inclusivity. Such a focus is also not confined to those in the innovation systems field; see for example Sen (2002). As a result, the Globelics Thematic Report (GTR) of 2011/12 defines inclusive development in a very different way to Kanbur and Rauniyar (2009) above. The GTR of 2011/12 defines inclusive development as:

“a process of structural change which gives voice and power to the concerns and as-

pirations of otherwise excluded groups. It redistributes the incomes generated in both the formal and informal sectors in favour of these groups, and it allows them to shape the future of society in interaction with other stakeholder groups.” (Johnson and Dahl Andersen, 2012: 25).

As a result, some have argued that any analysis of health innovation should focus at the level of the ‘local’ only because it lends itself well to the study of specific issues where inequality and social exclusion are major issues, e.g. health (Cassiolato and Soares, 2015). From a political economy perspective, Srinivas (2012) argues in a similar fashion that studies of innovation systems need to focus on the importance of sub-level systems because of the growth of urban centralised innovative activity. Such perspectives are important because of an increasingly dominant emphasis placed on global level action, especially in light of globalisation and the argument that ‘we are all connected now’ (Lee, 2003). Such arguments gain momentum as a result of global health outbreaks such as severe acute respiratory syndrome or SARS, Ebola or Zika. That said, there is no doubt that global level forces have shaped and continue to shape health systems strengthening efforts at a national level as the discussions above on the emergence of new actors and debates highlights.

Thus, in this vein, this report is written from the perspective that all activity within any system of innovation *should* work to meet developmental goals

of the communities impacted.⁵ This increasingly means finding creative ways of maximising both business and social value at both local and global levels. That said, this report focuses specifically on considering these issues from the perspective of nation states; this is because it is here that health systems are primarily devised and supported.

With regards to specific studies from the innovation studies field within the health sector, studies focus on many aspects of health related social development from water and sanitation (Cozzens and Catalan, 2008) to the development of new medical technologies (Arocena and Sutz 2012; Bianchi, 2014) and access to rural health services (Kraemer-Mbula, 2013).

Most of these studies reflect the need to add a normative dimension to innovation policy and related policies of trade, industrialisation etc. The studies are often set within a specific framework focusing on the importance of inclusion and the need for innovations to meet the needs of the poorest. This mirrors calls within the health policy field to ensure an equity and equality stance to health policy (Piot, 2012; Wagstaff, 2002). There

5 While this is how it all ought to work; this is not how it often realistically works. In reality there are many other issues and interests at play – including not least the profitmaking imperative of the private sector – that means that innovation systems do not necessarily work to the benefit of the communities. The result is that are both winners and losers of innovation.

are a number of studies that now empirically show (through in-depth analysis of case studies) that locally focused health innovation policy and systems that focus on meeting inclusion, equity and equality goals can work in a number of different settings around the world (see Cassiolato and Soares, 2015, for one compendium of such cases).

The extension of this argument is that, by having normatively focused policy, it provides the opportunity for the right forms of innovation to be developed. However, this depends, ultimately, on the quality of the system available, i.e. whether one is working within a system characterised by ‘abundance’ or ‘scarcity’ (Srinivas and Sutz, 2008). Frugal innovations are considered key here (Sutz, 2014). Such a focus is similar to discussions that have taken place within the cross-over area of health and innovation discussions around the role of disruptive innovations (Smith, 2007; Hwang and Christensen, 2008; Brook, 2009) and discussions on how to make health innovation more ‘valuable’ to meet ‘downstream’ (health outcome) issues (Lehoux et al., 2008). Frugal innovation is important here (Jamison et al, 2013).

There are also a set of discussions on the type of policy support required and where policy support is provided. Recognising that policy and action doesn’t occur in a vacuum, especially in a dynamic and evolutionary system, the change in one area of policy will not always lead to everyone ‘winning’ and can lead to situations of ‘policy resistance’ (Kraemer-Mbula, 2013). Others have therefore suggested that focus needs to be on policy implementation more than policy development (Mugwagwa et al., 2015)

Summing up

This Chapter has outlined the different types of thinking with regards to definitions of health, health systems and health systems strengthening since the WHO first defined health in 1948 to the present day. These discussions – within the health, international development and innovation fields – have been influenced by, and help shape, a series of key events, publications and debates; some of which have been outlined in brief above.

This Chapter has specifically reflected on the first two rows of Table 1, as outlined in Chapter 1:

Health as a means to economic growth	Health as a means to achieve social development and reduction of inequality	→	Health as an integrated element of and contributing factor to economic and social development built on equity and inclusion
Health as absence of disease	Health as wellbeing	→	Health as wellbeing

It has discussed different thinking put forward as to how health may be defined. Following this review, the report will define health in a much wider sense than simply as the absence of disease and illness to incorporate issues of wellbeing.

This Chapter has also introduced the interconnections between health of populations and economic and social development and the major debates with regards to these interconnections, including those from within the innovation studies fields. Following a review of these debates, this report takes as its starting point the idea that health is an integrated element of, and contributing factor to, economic and social development.

The report takes specific cognoscente of the power and politics flows within these debates and how these determine whose arguments are discussed and

acted upon in health policy and practice arenas. As such, the report will discuss how best to strengthen health systems and the relationship between health and economic or social development to encourage equity and inclusion.

In so doing, it takes a normative position on what the goal of health systems should be. Health systems are in this context seen as comprising the building blocks of leadership and governance, financing, human resources, the inputs of products and technologies, information and research as well as service delivery. However, this report will place an emphasis on not only these building blocks but also, and more importantly, the issue of interconnections and complexity within systems. These systems are the subject of the latter part of the next Chapter.



Tosamaganga hospital: maternity ward (Photo: Medici con l'Africa Cuamm, 27/1-2012.
<https://www.flickr.com/photos/mediconlafrica/8401509513>)



Hospital Geral de São Mateus, infant ward (Photo: Alexandre Moreira/A2 Fotografia, 8/4-2014. <https://www.flickr.com/photos/governosp/13722499764>)



3. Rethinking health innovation

Key points

- 1 For the promotion of improved wellbeing and sustainable livelihoods there is a need for system level changes
- 2 This requires social innovation in multiple spheres not just technological (product) innovation
- 3 This social innovation creates the learning and competence building that enables a system to adapt and change to new circumstances
- 4 One approach to recognising the importance of social innovation for technological product innovation has been the promotion of the concept of 'health innovation systems'

The two pictures (previous page) show a maternity ward in Tanzania and an infant ward in Brazil. At first glance, they suggest very different experiences and quality of care available based on the differences in equipment and general surroundings shown in the photos. However, the key to good health outcomes for maternal and child health – as

with any health aspect – is the quality of care and not just the latest equipment. Since the first 'Good health at low cost' report in 1985 (Halstead et al., 1985) there has been increasing recognition that examples exist of countries managing to achieve high rankings in health outcomes indicators despite not being able to spend huge amounts per capita on health facilities or necessary technology or human resources for these facilities. The first report singled out countries such as Cuba and the Indian state of Kerala while a 2011 follow-on report highlighted the examples of Bangladesh, Ethiopia, Kyrgyzstan, Thailand, and the Indian state of Tamil Nadu (Balabanova et al., 2013).

Key to the success of countries like Cuba, Bangladesh and Ethiopia have been process, organisational, institutional innovations as well systems level action, and not just access to new technological product innovations. The introduction of these – what we term 'social innovations' – assists and enhances further the strengthening of the health systems creating a mutually reinforcing cycle.

Therefore this Chapter introduces a discussion of different definitions of innovation, collapsing them into two overarching types: technological (product) innovations and social innovations. It should be noted that classifying the innovations in this way does not correlate to many definitions from the economics field. Schumpeter (1934), for example, discussed the existence of five different types of innovation: product, process, markets, supply/materials or business models. Schumpeter's 'product innovation' we equate with Jin's (2005) definition of 'hard technologies' or technologies that are in fact physical artefacts. The last four of Schumpeter's innovation types we categorise as types of social innovations. These include Jin's idea of 'soft technologies' or the combinations of knowledge, skills, routines and organisation required to operate a physical artefact (Mokyr, 2003; Burgess and Gules, 1998) but also, which artefacts are necessary for the operation of any social activity. In this way, it is similar – but again fundamentally different – from the definition of social innovation used in the business management literature. Social innovation definitions in this literature range from that which sees it as anything that isn't product innovation to, increasingly, the idea that it is any innovative activity that has a social purpose, i.e. benefits society as opposed to benefitting business (Pol and Ville, 2009).

The way we use the concept of social innovation fits the definition already in use within discussions on health innovation. Specifically, Gardner

et al (2007) see social innovations as those that are not product innovation and which build systemic capabilities (while recognising that they are intertwined and difficult to separate). In this vein, interestingly, the World Health Report 2013 argues that research is needed which "must explore the development and use of both "software" (such as schemes for financial protection and simplified approaches to treatment) and "hardware" (research and development for commodities and technology)" (WHO, 2013: p. xii).

The Chapter then goes on to discuss how the idea of social innovation is well suited to the idea of systems thinking and introduces the notion of a 'health innovation system'. Literature from within innovation systems thinking focuses on how forms of social innovation (as defined by us in this report) are essential for the development and strengthening of systems capabilities. Despite the idea that product innovation can create and encourage industrial development (UNIDO, 2016), these other types of innovation – especially institutional and organisational forms of social innovation – assist in this process and strengthen the likelihood of sustainability of health systems at large.

Unfortunately, the field of health and health-care around the world is still focused heavily on product innovation which can be seen in the solutions being put forward to tackle health problems. Thus, this Chapter finishes with an exploration of the extent to which social innovation is a focus of attention in policy and academic circles.

Types of innovation

The debates introduced in the last Chapter regarding the best means to improve health of populations can be traced back many years starting in recent history from the Alma Ata conference of 1978. This conference marked the first international gathering of individuals calling for comprehensive healthcare packages and 'health for all'. It led to a division in the healthcare community about the best way to develop healthcare and healthcare systems, sharpened by the international economic crisis of the 1970, to focus on comprehensive or selective healthcare interventions (UNICEF, 2008). These debates were the precursor for the next four decades of debates on the pros and cons of single issue/ top-down/ vertical/ medicalisation approaches as opposed to comprehensive/ bottom-up/ horizontal/ social determinants led approaches. Many of these debates focus on the relative merits of focusing on technological (product) innovations or social innovations.

There is now a much stronger recognition of the need to look past many of the dichotomous debates of the past relating to whether interventions should be top-down or bottom-up in development or whether planning should be done vertically by health issue or horizontally for the system as a whole. Since the mid-1990s with the increased interest on more nuanced health policy analysis and, more recently, the focus on understanding health systems more effectively, it would appear that the balance of opinion has swung in favour of the comprehensive, horizontal debates;

as the recent calls and action towards universal health coverage suggests.

However, the rise of the product development partnerships (PDPs) and global health initiatives (GHIs) in the late 1990s and 2000s has kept the spotlight on technological product innovation even though many of the PDPs and GHIs have been integrating elements of health systems strengthening into their activities. Thus there is still a context of controversy as, particularly for the global health initiatives (Hafner & Shiffman, 2013; Marchal, Cavalli, & Kegels, 2009; Storeng, 2014), to whether health systems strengthening is still too narrow in its focus and dominated by technical solutions rather than systemic approaches that focus on more holistic efforts. These debates also rage in the research arena on health systems strengthening (see Adam et al., 2012b; Frenk, 2010).

This report discusses the existence of two overarching types of innovation (technological product innovation and social innovation) as a result of two dichotomous approaches within the health field to the solutions needed for improvements to a country's health and wellbeing. Technological innovations are those new combinations of elements to produce hard technologies (new or improved products or artefacts). Social innovation then becomes a 'catch-all' category for all other forms of innovation including improvements in the process of production or delivery of a hard technology as well as new or improved organisational or institutional arrangements.

Definition of health innovation: new products or processes, organisational and institutional arrangements that are new to a context or new to the world, which create public health value or reduce disease burden leading to improved livelihoods and wellbeing.

Our definition of health innovation in this context is based on the recognition that the majority of innovation is not ‘radical’ in its activity – it does not bring wholly new products into existence – but is primarily the result of incremental innovation or small changes in the way products and processes are made and delivered. At the same time, and allied to this, there is recognition in many sectors that basic science has not been where most innovation occurs (Chalmers et al., 2014 cited in Chataway et al., 2015). Similar findings and arguments have been made in the global health field where it’s widely recognised that there has been a slowing down of the identification of new chemical entities reducing the number of new drugs on the market, particularly for neglected diseases of the poor (Lancet, 2011; Grabowski and Wang, 2006; Pedrique et al., 2013; Pecoul et al., 1999). It also mirrors calls in the global health field for a need to move beyond patents and publications and focus on the real health needs of those more affected by health problems through new financing mechanisms (e.g. Correa, 2012).

Technological (product) innovation

The development of new products and their subsequent introduction to new contexts has long been

an important boost for health and healthcare. Examples include: the immensely improved ability to treat infections with the introduction of penicillin; the ability to eradicate small pox after the introduction of the small pox vaccine; the massive impact that the availability of anti-retroviral drugs has had on the HIV/AIDS incidence and mortality rates and; the impact of SMS-texting services in increasing access to services or drug compliance.

The impact, and potential benefit, of different forms of technological innovation have been discussed in terms of ‘revolutions’, particularly in the recent past. The 2000s were heralded as the start of a biotechnology revolution for the healthcare industry, while some saw it as the start of an era of revolutionary genomics. The 2010s have been heralded as a digital revolution for the healthcare industry while others are enthused by the potential of nanotechnology and newer emerging technologies such as 3D printing. Each of these – neatly for us – provides a way of classifying different types of technological product innovation that have been important for improving healthcare provision options and reducing mortality or morbidity in recent years, starting with the precursor revolution relating to so-called ‘blockbuster drugs’.

The blockbuster drug and new chemical entity revolution

Following World War 2, the pharmaceutical industry – predominantly focused in high income countries – became increasingly vibrant with the development of in-house R&D facilities and dedicated

search strategies to locate new chemical entities (Malerba and Orsenigo, 2002). The result was that by the 1980s the world was witnessing an era of so-called ‘blockbuster drug’ development of drug products with a value of between US\$ 300 and 3000 million (Achilladelis and Ankonakis, 2001). Examples of blockbuster drugs are Lipitor (atorvastatin), a cholesterol reducing statin developed by Warner Lambert in the mid-1980s; Plavix (clopidogrel), an anti-blood clotting drug developed by Sanofi and; Actos, an anti-diabetes drug developed by Takeda (Hannigan et al., 2013).

The blockbuster drug revolution was supported by the emergence of biotechnology which enabled much more targeted screening of new chemical entities (NCEs) and compounds (Achilladelis and Ankonakis, 2001). At the same time it was hampered by a slowdown in the ability to find NCEs (Grabowski and Wang, 2006) (although new data (Ward et al., 2013) suggests that by looking over a longer period of time there is not a large reduction in the discovery of NCEs).

Unfortunately, many low and middle income countries were unable to access blockbuster drugs due to the intellectual property regime in place at the time. This made these drugs prohibitively expensive for low and middle income country governments with limited financial resources. At the same time, most of these drugs focused on treating illness and disease that was less prevalent in low and middle income countries in the 1980s and early 1990s. Organisational and institutional innovations to incentivise development of appropriate

medicines and make them available at lower cost will be discussed under social innovations below.

The genomics and biotechnology revolution

The development of biotechnology not only made the search for NCEs easier but has also been seen as heralding in the opportunity to solve the world’s health problems (Singer and Daar, 2001). Biotechnology involves the utilisation of organisms found in the human body as well as outside (e.g. bacteria) to make useful products, such as vaccines or a diagnostic product. The related area of genomics is the study of genes in humans or animals and the relationships between these genes. There are therefore several ‘genome projects’ which focus on mapping all the genes inside a human being or animals like mice or monkeys or mosquitos in order to understand how disease and illness occurs and how the body reacts to disease and illness.

The genomic era is heralded as having started with the sequencing of the human genome in 2003 (Guttmacher and Collins, 2003). In recent years, we have witnessed an increase in the ability to use genomic medicine and science to help produce new curative treatments in the form of things like stem cell therapies for blood and immune system conditions and disease and some cancers. However, the study of different genomes in humans but also in animals and insects has been heralded as leading to important discoveries with respect to many tropical diseases and diseases affecting resource-poor environments around

the world. Specifically genomics (and biotechnology more generally) is said to provide (Daar et al., 2002; Pang, 2009):

- Faster identification of pathogens for improved detection of disease
- Cheaper, quicker and more accessible point-of-care diagnostics
- Improved vaccines and drug discovery and development as well as enhanced monitoring of resistance to vaccines and drugs
- More effective vector control mechanisms

While the genomic era and the biotechnology revolution was heralded as creating opportunities for a range of therapeutic and preventive applications for improved health, some have argued that the idea is a 'myth' following a traditional pattern of incremental technological diffusion (Nightingale and Martin, 2004). Others highlight that the traditional barriers and challenges to the use of such technologies, including lack of training and knowledge, poor facilities and funding, still plague many resource poor countries; despite some examples to the contrary (Coloma and Harris, 2009). As such, the idea of a 'post-genomic era' is common. With this concept, scientists and researchers recognise that, while the introduction of the study of genomics has created a plethora of potential areas of analysis and investigation, there is still a huge gap existing between this and the resulting creation of new drugs, vaccines and diagnostics (Chanda and Caldwell, 2003).

The digital healthcare revolution

A Goldman Sachs 2015 report talks of the potential afforded by a digital healthcare revolution to drastically change the way healthcare takes place and reduce the soaring costs of healthcare in the US. It argues that information communication technologies (ICT) will allow for the increased provision of healthcare advice at a distance through telehealth and e-health options. Such thoughts have also been echoed in terms of the potential for e-health and ICT technologies to transform healthcare in resource poor settings. Of particular interest are:

- The potential of telemedicine to increase access to qualified medical advice at a distance through online communication and file sharing mechanisms;
- Mobile phone apps that remind individuals to take their medication at particular times or of the timing of anti-natal classes or children's vaccine schedules
- Decision support tools to enhance the administration of hospitals and clinics providing computerised patient records, for example.

Despite all the enthusiasm, there are also words of caution as a result of the difficulty to scale up many of these examples that are still at a pilot stage (Green, 2010; Westbrook et al., 2009). That said, the continued success of the diffusion of mobile phone technologies in resource poor settings in Africa keeps momentum on the potential that such technologies may have. A further new

turn in these discussions is the role of 'big data' and the use of large datasets that can be analysed with high powered computers to chart potential impacts of epidemics or the future trends in disease (Hay et al., 2013.).

Emerging and converging technologies

The list of product based technological revolutions in healthcare continues. For example, nanotechnology – the use of minute materials to produce new products – became a key issue for discussion following the biotechnology and genomic revolutions. It is argued to provide opportunities for more effective drugs, vaccines and diagnostics while nanoparticles can also lead to the creation of medical devices that are more durable (Bennett-woods, 2011). In the ICT sector, interest is turning to the use of 3D printing as a means to provide custom made prosthetics or medical devices (Michalski and Ross, 2014). Finally, there is increasing recognition that many of these technological advances are being used in combination, creating the concept of 'converging technologies' (Bainbridge, 2003).

The two sets of overarching fields of focus (health policy and innovation studies) come at the importance of technological product innovation from two very different perspectives. For those from the health field the emphasis is on how these innovations can lead to improved healthcare solutions thus reducing illness, disease burden and premature deaths across the population. The majority of the literature outlined above focuses on the latter element; the ultimate impact of these technologies on

health. A sub-set of literature focuses on the impact of these technologies on health service delivery and improvements in healthcare provision.

That said, in several industrialised countries, health policy is increasingly recognising the relationship between health innovation and economic growth. One such example is the Academic Health Innovation Networks in the UK, mentioned earlier in this report. A 2015 impact report on these networks' activities highlighted how the networks created 138 new business opportunities through contracts, leveraged 10 million GBP of funding, and several have developed contracts with overseas companies to license in products, sell products abroad or work on collaborative R&D products (ASHN, 2015). In some countries, the pharmaceutical industry is a large contributor to the economy. China, through its 'Key Drug Innovation' project in 2007, has been massively investing in the sector in order to increase the percentage share of the pharmaceutical industry in its economy (Hu et al., 2016).

Unsurprisingly therefore, there is a stream of research within the innovation studies field that has investigated the impact of health product innovation on economic growth paths. This includes research very squarely focused on the history and structure of the sector (Pisano, 1997; Malerba and Orsenigo, 2002; Garavaglia et al., 2012). There is research investigating the costs of the pharmaceutical development process and implications on the sustainability of the pharmaceutical sector (c.f. DiMasi et al., 2016 and the work of the Tufts Center for the Study of Drug Development). Oth-

er research investigates the pharmaceutical and biotechnology sectors and how to promote their innovation systems (c.f. McKelvey, 2008; McKelvey et al., 2004). More broadly, there is work that focuses on the impact of the pharmaceutical sector as a driver for catching-up and/or industrialisation (c.f. Mackintosh et al, 2016; Srinivas, 2012; Gadelha et al., 2008; Huang, 2012; Ramani and Guennif, 2012).

Much of this latter work has focused on the social innovation required for successful product innovation. Issues that are discussed in this literature are related to the intra-organisation of firms and business models that are utilised. Other issues addressed include the inter-organisation of firms, networking and partnerships undertaken. A further set of issues address the institutional environment that pharmaceutical firms and other product technology firms are influenced by, such as the regulatory environment and the level of public funding of health R&D.

Social (process, organisational, institutional and systems) innovations

Thus, product technology innovation is dependent on allied social innovations. These can be innovations that improve the way a product is produced (process innovation) or the way products are used by healthcare professionals and delivered or used to patients (organisational innovations). Also important are informal and formal ‘rules of the game’, the underlying values and norms that determine how products are introduced and used (institutional

innovations). Less often considered, but perhaps more important, are also systems innovations that refer to the competence building connections that ensure that all the other forms of social innovation as well as product innovation can be successful.

As such, some scholars (Jensen et al., 2007) have made the distinction between two modes of innovation. The first mode of innovation they term the ‘science, technology and innovation mode’ (STI-mode) while the second they term the ‘doing, using and interaction mode’ (DUI-mode). It is argued that without the latter, the former cannot be successful (Freeman, 2002). The idea of STI mode innovation is based on the fact that the introduction of some new technologies can take place as a result of the production and use of codified knowledge; knowledge that is written down and easily conveyed from one person to another. The blueprints for a new medical device design or the recipe for a new drug formulation are such examples. However, there has been increasing recognition of the importance of DUI modes of innovation both in their own right and for the successful completion of the STI mode of innovation. In the DUI mode of innovation, the emphasis is on the creation of new technologies through informal learning processes and tacit knowledge. Nelson (2008) discuss the relevance of the DUI mode or ‘social technologies’ for the STI mode or physical technologies through the lens of cookery:

“...a recipe characterisation of what needs to be done represses the fact that many

economic activities involve multiple actors, and require some kind of a coordinating mechanism to assure that the various aspects of the recipe are performed in the relationships to each other needed to make the recipe work. The standard notion of a recipe is mute about how this is done... [We] propose that it might be useful to call the recipe aspect of an activity its “physical” technology, and the way work is divided and coordinated its “social” technology.” (Nelson, 2008:1-11)

As outlined at the start of this Chapter, we see social innovations – what some refer to as social technologies and the WHO has discussed as ‘software’ technologies – as referring to improvements in the process of production or delivery of a hard technology as well as new or improved organisational or institutional arrangements. In addition, it also covers the issue of systems level connections that are necessary for effective learning, capability building and knowledge flows aimed at ensuring a well-functioning health system.

Process innovation and intra-organisational innovation

Process innovation relates to the ways in which a technological product innovation is improved through changes in its production process (Schumpeter, 1911 cited in Edquist et al., 1998). Process innovation can be divided into that which is technological (i.e. the introduction of robots into the manufacturing process to increase accu-

racy of manufacturing) or it can be organisational (i.e. the introduction of new ways of managing the factory floor such as the use of ‘lean production’ techniques) (Edquist et al., 1998). Process innovation was traditionally argued to take place later in the lifecycle of a product when first-mover advantage had been lost and incremental innovation was being concentrated on (Utterback and Abernathy, 1975). That said, there has been recognition of the importance of process innovation throughout the product innovation lifecycle, especially in high-tech sectors such as the pharmaceuticals sector (Pisano, 1997).

This report has placed process innovation within the category of social innovation and not technological innovation. Our decision is based on the recognition of the underlying importance of learning and knowledge on process development activities (Pisano, 1997) within health systems and a focus on health systems and not simply firm level innovation.

Therefore, to the extent that we can focus on individual firms, this report is predominately interested in the role of organisational level process innovation changes within a firm’s production activities. In this context, process development at firm level is “a capability-creating activity involving the translation of technical knowledge into operating routines.” (Pisano, 1997: 26).

Increasingly, the discussion on such intra-organisational process innovation in firms involved in health innovation cannot be divorced from inter-organisational innovations. This is because of the

increasing movement from what has been termed Schumpeter Mark I to Schumpeter Mark II forms of innovation whereby firms move from innovating in isolation (Mark I) to innovating through networks (Mark II). It has been put forward that firms are increasingly having to integrate knowledge internally from multiple sources (Hobday et al., 2005), or, become knowledge brokers, meaning that they have the skills to find the knowledge and capabilities required and work to bring these together from a diverse set of locations (Brusoni et al., 2001).

Thus, this report also recognises another form of process innovation; the introduction of new approaches to how healthcare delivery is undertaken. An example of such a process innovation would be a shift from pre-booked appointments to a 'drop-in, first-come-first-served' system of doctors' appointment within a health service facility to increase throughput of patients. Another example would be the introduction of Six Sigma or Lean production into hospital care to enhance the quality of services provided at the least cost (de Koning et al., 2006).

Inter-organisational innovation

As outlined above, health innovation has increasingly become much more networked and collaborative in recent years; including through mergers and acquisitions or takeovers (Grabowski and Kyle, 2008). These are seen as a means of boosting internal capabilities and of 'systems integration'. Higgins and Rodriguez (2006) found that in a survey of 160 pharmaceutical acquisitions reviewed between

1994 and 2001 the vast majority had led to positive gains for the companies. In fact, it is possible to argue that it has become commonplace to assume that biotechnology firms would reach a certain size and then be bought out by a larger pharmaceutical firm who had the funds to take product development to the expensive clinical trial stages.

However, while originally these mergers and acquisitions led to large firms with all the capabilities bought in-house, increasingly the nature of systems integration is changing. On the one hand, you have the internalisation of biopharmaceutical R&D within large pharmaceutical firms reducing the need for specialist biotechnology firms (Niosi, 2013). On the other hand, there is an increasing focus on contracting out various elements of the pharmaceutical production process to multiple companies around the globe in the form of outsourcing increasingly offshore in emerging economies such as India (Krishna et al., 2012).

Changing inter-organisational relations aren't confined to only those between private for-profit pharmaceutical and biotechnology firms, as debates with regards to the role of the public sector in health product innovation highlight. In fact, the role of the public sector in financing basic science in a number of key areas has been recognised of late (c.f. Mazzucato, 2015). Two-thirds of all funding for neglected disease R&D currently comes from high income governments and multinationals, according to the 2015 G-Finder report. The US government, through its National Institutes for Health, provides two thirds of this funding (Policy Cures, 2015).

In the arena of global health and the development of drugs, vaccines and diagnostics for diseases predominately affecting low income countries, the majority of the collaborations with government funded basic and applied science institutions take place through what have been termed 'global health partnerships' or as PDPs (Policy Cures, 2015; Polastri, 2014; Chataway et al., 2011). PDPs started in the mid-1990s but gathered momentum in the 2000s as a means of encouraging collaboration between pharmaceutical companies and non-profit actors to search for new or improved solutions to the world's health problems (Buse and Walt, 2000; Buse and Harmer, 2004). Their efforts have resulted in the commercialisation of new drugs, significant leads in the development of new vaccines and diagnostics as well as capacity building efforts through the building up of new research staff and facilities in a number of low income countries around the world. Perhaps more importantly, PDPs as an inter-organisational innovation create the opportunity for the essential 'learning by doing' that is required for successful product development to take place, recognising the difficulty of simply promoting the STI mode of innovation (Mahoney, 2011).

The difficulty, outside of PDP type mechanisms, for universities and public research institutions to link with commercial companies in low and middle income countries has been catalogued well in Latin America. Rodriguez and Dutrenit (2010), for example, have highlighted how Mexico has weak Public Research Organisations (in the form of universities and public research institutes) in terms of

capacity and capabilities, and local health innovation firms weak in absorptive capacity to work with them. However, this is not always the case as the experience of Fiocruz, the largest public health research institute in Brazil, with GlaxoSmithKline (GSK), the multinational pharmaceutical company, shows (Porto et al., 2012). The partnership between Fiocruz and GSK has led to a number of drugs and vaccines being developed since the start of their partnership in 1985 including the introduction of some of them, notably the dengue fever vaccine, being added to the national immunisation schedule in 2010.

However, organisational innovation in the healthcare sector is not only about the coming together of private firms or private firms with public entities. There is also a wider set of inter-organisational innovations that have been taking place and that are promoted to create more effective product innovation and improved healthcare services. These other organisational innovations relate to the creation of clusters of organisations as a result of arguments that proximity and location matter in creating improved opportunities for innovative activity to take place (Cooke, 2001). For example, India's pharmaceutical sector is predominately centred around key urban centres, where internationally renowned medical schools and universities feed the sector's need for qualified researchers and technicians (Athreye et al., 2009). In Brazil, the Minas Gerais pharmaceutical cluster is similar (Cassiolato et al., 2011). Biotech clusters were initiated in Egypt and South Africa in the early 1990s to enhance pro-

ductivity in the sector (Uctu and Pillay, 2012). In Pakistan, a surgical instrument cluster in Soilkot is the second largest producer of surgical equipment in the world (the first being in Germany) and it has survived and thrived because of the proximity of the different manufacturers to each other (Navdi and Halder, 2005; Haneef, 2016).

In these previous examples of inter-organisational innovation, the networking and collaboration have taken place in order to bring together discrete knowledge or capabilities so that new products or healthcare solutions can be developed and diffused. However, organisational innovation can also take place as a result of what has been termed ‘scarcity conditions’ (Sutz, 2014). Situations where there is a strong demand for new technologies or more efficient technologies but a lack of interest by traditional players (i.e. established for-profit firms) result in making other actors come together and develop health innovation where they normally wouldn’t. Such innovations are what can be termed ‘below the radar innovations’ (Kaplinsky et al., 2009) in that they are not readily known about, or considered as important, by governments and other relevant stakeholders.

Again, much of the above discussion has so far discussed inter-organisational innovation relating to the health product innovation process. However, inter-organisational innovation is also proving important in healthcare delivery. This involves the contracting out or empowerment of new forms of staff to undertake new or alternative roles in the healthcare delivery system (sometimes referred to as

‘task-shifting’) or the use of alternative, community based, health clinics for basic services using nurses rather than doctors surgeries (Robinson and Smith, 2008; Goodman et al., 2010). For example, El Ari-feen et al. (2013) highlight how a move towards the use of community level health personnel in Bangladesh in routine healthcare resulted in improved healthcare services. In Zambia, community health assistants are being deployed to bring health workers to communities and improve health service delivery (Zulu et al., 2015).

These discussions have focused on country level inter-organisational innovations. However, increasingly, as a result of globalisation, the networks and collaborations between organisations take place across geographical boundaries. There is some interesting work that has been considering the potential value of South-South partnerships and collaborations, i.e. those between different organisations based in various low and middle income countries, over the more dominant North-South partnerships and collaborations (Thorsteinsdottir and Chaturvedi, 2014; Thorsteinsdottir et al., 2010). This fits within wider work from innovation studies that considers the relative merits of innovation originating from India or China for Africa (c.f. Kaplinsky and Hanlin, 2016) because the former is seen to be designed with those operating conditions and cultural contexts in mind that are also found in the African context.

Institutional innovation

The importance of institutional innovation is often overlooked in health policy discussions. However, facilitatory institutions and institutional arrangements are fundamental for successful innovation of any type (technological, project or organisational in nature). There are three main areas where institutional innovation is necessary. These are in the areas of governance, regulation and finance.

Institutions are often defined as ‘rules of the game’ (c.f. North, 1990). These can be formal rules and laws as exemplified by government legislation or international standards or they can be more informal rules and norms that reflect how people expect to live and work (these are sometimes referred to in terms of cultural norms). At the same time, institutions sometimes refer to organisations and organisational structures. Therefore, the state, i.e. government and its various organs, can be defined as an institution. In many instances, the state is juxtaposed against another institution, the market. In reality, these are not single organisations but are made up of multiple organisations (different ministries and organs of state on the one hand and different private for-profit and non-profit actors on the other). These come together to ensure that the state and market are key institutions that provide useful (or, in some cases, unhelpful) institutional innovations that help or hinder technological innovation and improved health services delivery. In addition, the state and market are themselves influenced by, and create, formal and informal rules of the game. The ways in which these multiple or-

ganisations can be and are combined in different countries and contexts differ and analysis of these combinations are required to a) explain differences in health outcome and b) improve policies for ensuring more equitable health outcomes. The 4Fs framework introduced in Chapter 4 provides one means to conduct such an analysis.

Considering issues of institutional innovation is important because - as others have argued in the case of African countries (Al-bader et al., 2010), while we would argue that it is relevant across the globe - there is significant health research going on, but this research often does not lead to the development of new technologies. The reason for this is partly the lack of positive institutional innovations, relating to regulation and global governance structures that are restricting the development of domestic capabilities.

Governance related institutional innovations

In recent years, the health innovation field has seen a number of governance related institutional innovations become prominent, especially at the global level. New actors on the global health innovation scene are changing the dynamics of health innovation and even healthcare delivery systems around the world. Notable here are the Global Fund for AIDS, TB and Malaria and Gavi; two global health partnerships that were created to incentivise health product development in the early 2000s. Another example is the Bill and Melinda Gates Foundation, which is the largest funder of health innovation outside of the US National In-

stitutes of Health (Policy Cures, 2015). These organisations have changed the way health innovation takes place, by disease, location and timeline, in terms of the focus areas considered. As such, these organisations are increasingly responsible for the ‘steering’ of both global and national health innovation activities.

The notion of ‘steering’ (as opposed to ‘rowing’) is used to explain the current concept of ‘governance’ (as opposed to ‘government’) in health innovation activities (Lyall and Tait, 2005). It links to the notion of ‘stewardship’ that was raised in Chapter 2 and a change in the way that attitudes to governmental control over health innovation and health systems strengthening has changed in recent years.

That being said, the rise of new actors on the global health scene and their governance role has not been without critique (Rushdon and Williams, 2009; Frenk and Moon, 2013). There is no doubt that GHPs have led to increased interest by global pharmaceutical firms in diseases affecting the poorest populations in the world. However, these firms are unlikely to change their business models and will remain dedicated to high income, high-return markets of the North. At the same time, newer firms in emerging economies that are becoming ‘ones to watch’ globally are also likely to focus increasing amounts of attention on the more profit providing disease profiles of the North; despite the changing epidemiological profile of lowincome countries (Chataway et al., 2011).

As such, there is still an important role to be played by national governments and state apparatus

in ensuring successful health innovation (Kale, 2013; Bloom et al., 2014 and; Arora, 2007). Specifically important governance related institutional innovations by the state include the provision of facilitatory rules, laws and policies for health innovation activities. Examples of where these have been provided include the promotion of linkages between stakeholders for pharmaceutical production and health service delivery in Tanzania (Szogs, 2014), Rwanda (Simiyu et al., 2010) and Brazil, India and China (Mcmahon and Thorstiansdóttir, 2011).

There is a further set of organisations that provide important governance related institutional innovation in the health innovation field, which until recently have often been overlooked: the industry associations (Papaioannou et al., 2015). These networks of organisations – such as the International Federation of Pharmaceutical Manufacturers or country level versions of the same or those related to doctors, nurses, pharmacists – are examples of organisational innovations. They are also facilitators of institutional innovations because they often have the ability to influence the norms, rules and values of their members as well as the wider health system in which they have influence.

Regulation and IPR related institutional innovations

The role of governments in supporting institutional innovations is played at an organisational level, a governance level and at a regulatory level. It is to this last area that we now turn. It has been argued

that governments play a key role in providing a supportive regulatory environment to those involved in health innovation; particularly domestic industry (t'Hoen, 2006). As such, there is a series of regulation related institutional innovations possible; some orchestrated at a national level and some – and perhaps increasingly so – at a global level. As with governance related institutional innovations, these innovations can have negative or positive effects on other innovation and health delivery efforts.

Perhaps the most obvious regulation related institutional innovation is also the most controversial one. This is the Trade Related Intellectual Property Rights (TRIPS) connected legislation around the world, introduced in the 1990s and updated in various ways since then. These on the one hand insisted that patent protection be upheld around the world (potentially increasing the cost of drugs but also giving firms more control over how and where their products were marketed). On the other hand, the laws also gave countries an opportunity to circumvent the rules and compulsorily license the production of copies of expensive drugs from abroad in local factories (potentially reducing the cost of drugs and increasing the potential for a viable local generics industry).

Some would argue that these IPR laws have been conducive to a country's innovative potential providing an opportunity for countries to move into new drug production areas (e.g. Rashmi (2011) with respect to India; Oliveria et al (2004) on Brazil). Others have been less positive about their impact (Urias and Furtado (2009) on Brazil or Guen-

nif and Mkufa (2013) on Thailand). This has not just been an argument for mainstream pharmaceutical production but also has played a role in the traditional medicines area (Madhavan, 2008).

A more recent, but no less controversial, regulation related institutional innovation is that of 'open innovation'. This term encapsulates the idea that firms no longer innovate in a 'closed' environment, i.e. in internal R&D labs, but instead must frequently connect and network with others to gain knowledge and skills for successful innovation (Chesbrough, 2003). Key to the success of 'open innovation' is the idea that there is no proprietary ownership of ideas but that firms and other actors collaborate freely although obviously in a way where each party gains. As such, there have been calls for less emphasis on publishing and patents and more on incentives to network and conduct research (e.g. Stiglitz, 2007)

Finance related institutional innovations

Another institution that is increasingly being recognised as important, particularly in light of the universal healthcare coverage discussions, is that of finance. The most well known of the finance related institutional innovations are again – as with the governance related institutional innovations – those that are based at a global level. Examples of these include the Advanced Market Commitments for pneumonia vaccines (Batson et al, 2006); an R&D fund (Balasegaram et al., 2015) and the more recent Global Health Technology Fund (<http://www.ghitfund.org/>). These were developed to

provide an incentive mechanism for the development of drugs, vaccines and diagnostics for diseases that were being neglected by pharmaceutical industry firms around the world. These are financial instruments that, in the case of the Advanced Market Commitments, are administered by Gavi. As such, they were designed with a similar but still different mandate to Gavi and the Global Fund for HIV/AIDS, TB and Malaria, which are organisations and not simply financial instruments. However, these latter organisational innovations have also been termed financial innovations by some authors (c.f. Atun et al., 2012).

These instruments have traditionally focused on large industry players – the globally active pharmaceutical companies from the North (the likes of GSK, Merck etc.) as well as the South (such as Cipla and Rambaxy from India). However, there is a significant amount of local manufacturing of medicines, i.e. in low and middle income countries for their home markets, especially in Africa (Mackintosh et al., 2016). Much of this manufacturing is not concerned with novel drugs or vaccines but with so-called ‘me-too’ drugs, i.e. copies of drugs that have come off-patent or generic drugs (Banda et al, 2016). The manufacture of novel drugs or the production of the active pharmaceutical ingredients to produce these drugs are costly exercises and a combination of economies of scale and high levels of regulation in the form of Good Manufacturing Practices prohibit many African countries, especially, in developing more advanced pharmaceutical production capabilities

(Mackintosh et al., 2015). In the case of African countries – where pharmaceutical production is at its lowest – it has been argued that what is needed are finance innovations, namely public procurement related instruments (Chataway et al., 2015) supported by facilitatory regulatory instruments such as conducive tax and duty regimes (West and Banda, 2015). However, above all, what is needed for African pharmaceutical industries to develop is good sources of foreign direct investment and to a lesser extent (because of its limited availability) venture capital funding (West and Banda, 2015). West and Banda (2015), however, state that these will not be useful if pharmaceutical firms – but also the financial firms – do not have the requisite capabilities or ‘know-how’ (Jensen et al., 2007) to understand the workings of the financial instruments or the market in which the firms operate. While West and Banda (2015) do not see much hope for venture capital funds at present for African pharmaceutical companies, this does not mean to say that they haven’t proved important players already. Masum et al. (2010) highlight the role of venture capital firms, such as Acumen Fund and Bioventures, for the development of a number of key health innovations in Africa and argue that venture capital does have a place for health innovation efforts on the continent.

Systems innovation

Finally, systems innovation - another form of social innovation - will be touched upon. The idea that you can have such innovation is relatively new in

the health policy field but has been an important part of the innovation studies literature since the 1990s. An example of this type of innovation may be derived from a review of the Tanzanian (when compared to Ghanaian) introduction of vouchers for malaria prevention (see de Savigny et al., 2012).

Tanzania introduced a pilot voucher scheme in the late 1990s, which was rolled out nationwide from the mid-2000s. Vouchers for a subsidised insecticide treated mosquito net were provided to women attending reproductive and child health clinics with 80% of nets being redeemed (de Savigny et al., 2012). In contrast, the Ghanaian scheme never succeeded because internal system functions were not enhanced. The authors argue that this is because “external ideas, events and actors were more prominent in driving events.” (de Savigny et al., 2012: iv42).

There has been increasing recognition in recent years of the need to think in terms of a health *system* as introduced in Chapter 2. What such thinking – both from within the health policy field (taking inspiration from complex adaptive systems thinking) and the innovation systems field – argue in this regard is twofold. First, successful innovation requires a recognition of all the actors involved, of how they fit together and then of the necessary practical steps to encourage them to work together. Recognising the different elements and actors involved in the innovation process, it is important to understand more deeply how they interact and the roles they play in the system. Second, in order for the actors to work together more effectively, there is a need to

understand how learning and knowledge is transferred between the different parts of the system to create a greater whole.

Systems innovation is about achieving the right mix of all other forms of social and technological innovation. Conceptually, this requires new ways of thinking about the definitions and processes of innovation and healthcare delivery.

Focusing on innovation and health systems level innovations

A number of innovation and health scholars and practitioners have been converging in recent years around the idea of ‘systems innovation’. This comes as increasing numbers of scholars and practitioners focus on wider definitions of innovation; on different types of social innovation and not just on product technologies. Alongside this are those that focus on the marriage of innovation systems thinking and health systems thinking. Allied to this, in turn, is a set of literature on the role of capacity building, especially scientific/biomedical research capacity building in low and middle income countries, and its ability to disrupt innovation pathways.

Much of this recognition comes from a set of wider discussions on how to understand and promote more effective global health policy, particularly with a focus on the impact for low and middle income countries. However, some of it – see for example Sakellarides (2008) – comes from discussions focused very much on European or North American based health systems.

At the centre of these discussions are a series of new systems based terms for helping conceptualise health innovation. These include: health innovation systems (Morel et al., 2005a); health innovation networks (Morel et al., 2005b) and; global health research and innovation systems (Matlin and Samuels, 2009). These concepts see innovation – as we do in this report – as encompassing a set of activities (organisational and institutional), processes or products which are new to a context (rather than new to the world) and which create public health value or reduce disease burden. In such a wider definition, health innovation refers to a range of different types of activity aimed at improving efficiency and efficacy in any or all of the WHO building blocks of a health system.

The development of the concepts of health innovation systems, health innovation networks and global health research and innovation systems came about because of an interaction with innovation systems thinking by those working in the global public health arena. The three terms are connected but different. The term 'health innovation system' was coined by Morel and colleagues (2005a) following a workshop in Bellagio in 2004 which brought together health scholars and innovation scholars to discuss how to move forward health product innovation for neglected diseases. They defined a health innovation system as including "interlinked components including education, R&D, manufacture, domestic and export markets, intellectual property management, regulatory

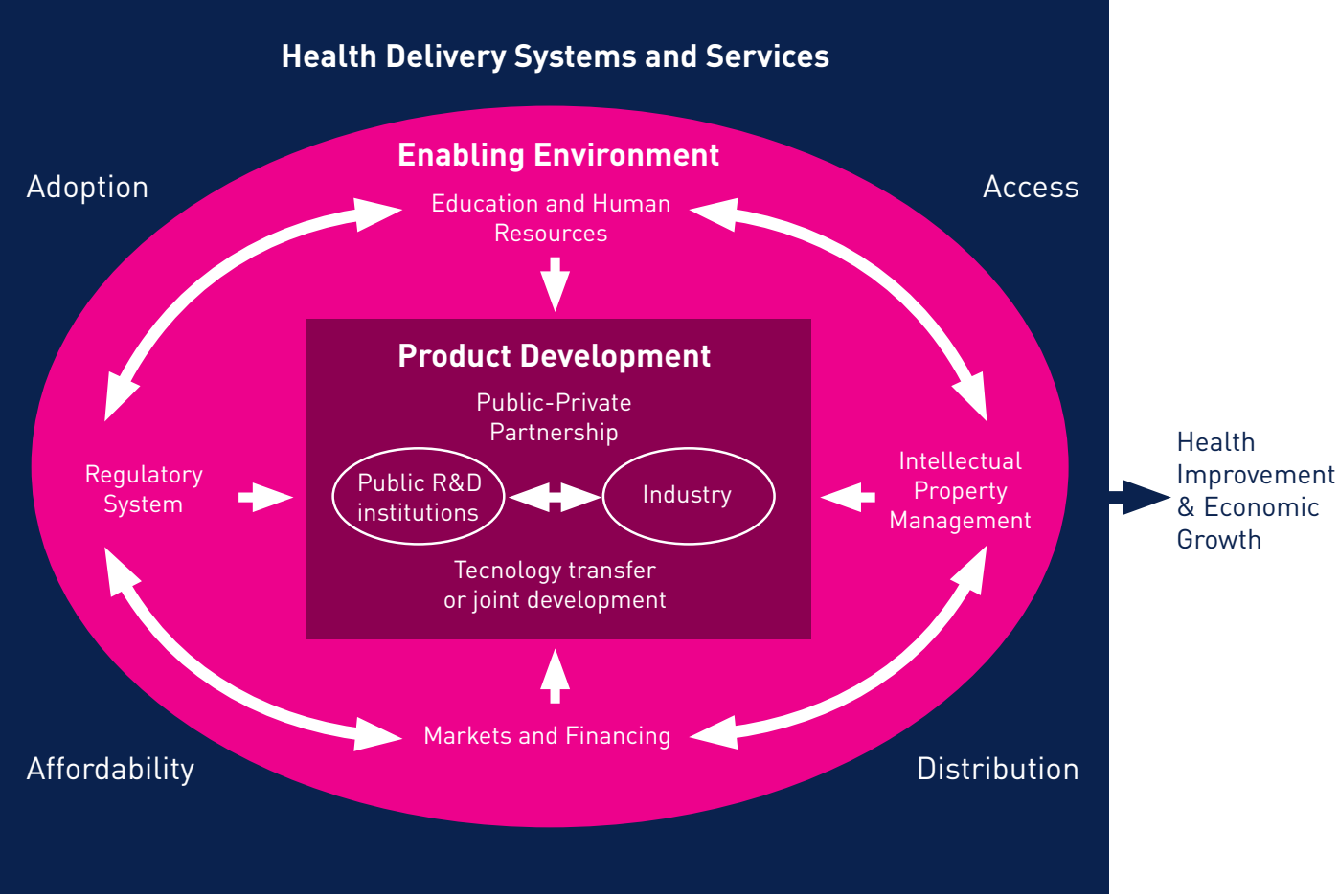
systems and the national policies that affect all of these (including public-private partnerships)."

Key to the success of a health innovation system, they argue, is the recognition of the interlinkages, the 'dynamics linkages', between the different elements of the system. They go on to argue (as do some of the authors in a similar paper; Morel et al. (2005b)) that recognising the global nature of innovative activity there is a need to focus on developing networks of actors involved in health innovation or 'health innovation networks', especially those involving South-South collaborations, to ensure maximum cross-fertilisation of ideas and action in the most relevant formats. The idea of a health innovation system has been diagrammatically visualised in Figure 3.

This field of thought was further enhanced by a paper in 2007 by Gardner et al., which focuses on the difference between technological and social innovation. It makes the point that technological innovation focuses on the development and deployment of 'cost-effective products', but more important than this - because technological innovation depend on them - are two other forms of innovation, namely social innovation or 'distribution mechanisms for essential goods and services' and, even more important, 'adaptive innovation' or the contextualisation of the first two types into local settings.

Two years later, a further paper (Matlin and Samuels, 2009) was published that moved the discussions in this area further forward, entitled 'The

Figure 3 A health innovation system for health products



Source: Morel et al. (2005b)

Global Health Research and Innovation System'. The paper described the need to look more closely at the 'overlapping domains of research and innovation' as a result of the increasing emphasis being placed on research for health and the 'growing complexity of the architecture of global health research'. The paper recognises technological innovation and social innovation *a la* Gardner et al. (2007) and argue that they are intertwined and complementary to each other. They see an intersection of activity in the middle of research systems and innovation systems where health research comes together. They see this happening within the context of a wider external environment of 'drivers, incentives and motivations, promoters and barriers' with positive and negative feedback loops. As such, the paper appears to draw on innovation systems thinking as well as systems thinking from the health field. Thus, they focus on different elements of the system as being both actors as well as innovative activity (to create products or processes), but they also focus on the flows and relationships between each of these as outlined in Figure 4.

Disconnects remain

Despite the rhetoric within recent reports of innovation or innovative solutions and the increasing emphasis placed on health systems strengthening, this set of literature that married together health systems, health policy and innovation systems approaches has not flourished. Although references are made to this literature – for example, Howitt et al.'s 2012 Lancet commissioned 'Technologies

for Global Health' report includes a definition of health innovation taken from the seminal paper introducing the concept of global health and research systems (Matlin and Samuels, 2009) – current global health discussions and, more importantly, country level debates, appear to shy away from thinking beyond innovation as a process in the development and commercialisation of a technological product.

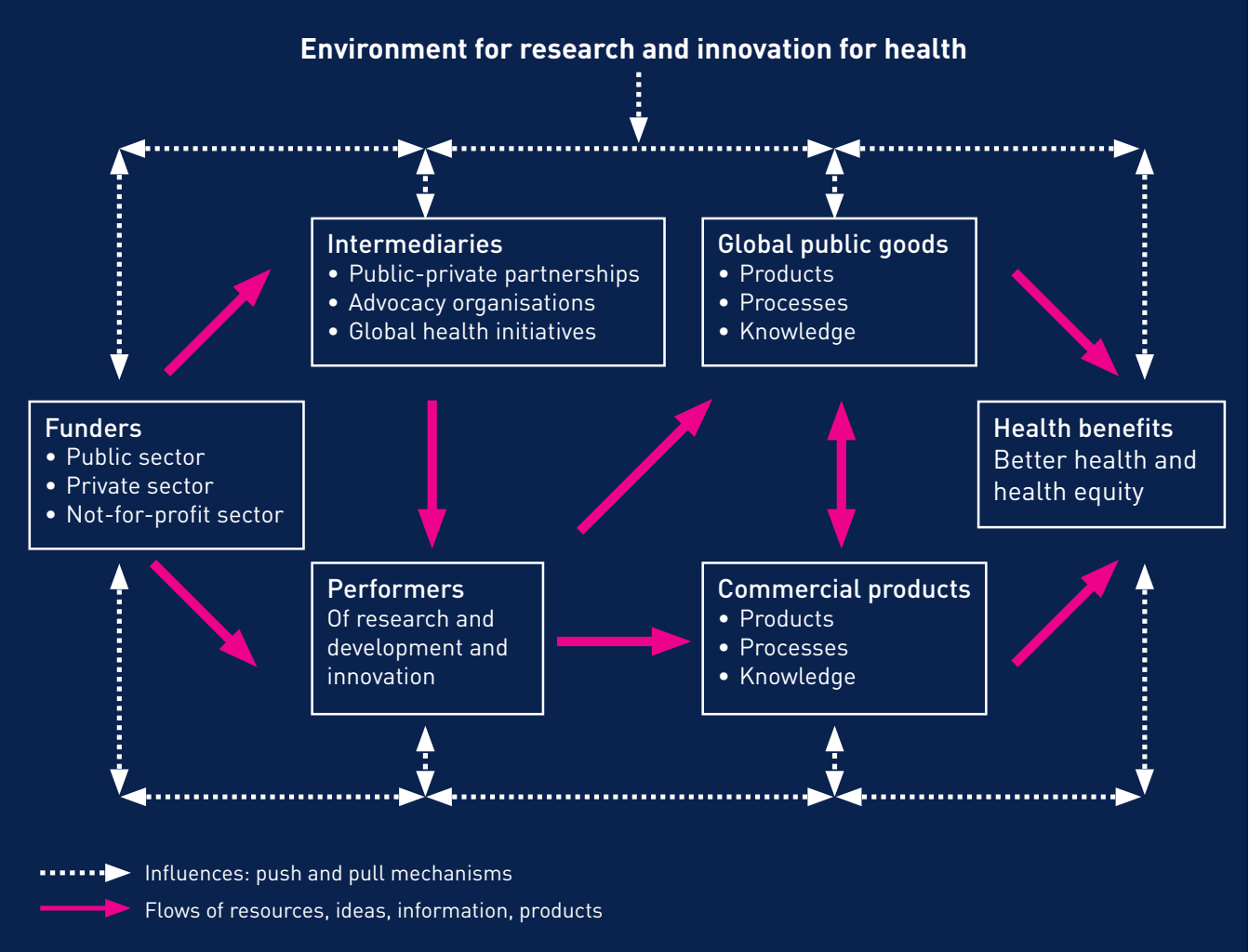
This difficulty in sustaining a momentum between health researchers and innovation research has been put down to the fact that the scholars involved in these discussions still come from distinct fields of thought which rarely come together (Hanlin, 2008; Srinivas, 2012; Sutz and Srinivas, 2008; Mackintosh et al., 2016). Others have recognised the difficulties also:

Lehoux et al. (2008): "Innovation designers rarely tap into the knowledge generated by health services researchers while health services researchers often fail to provide key insights about the *comparative value* of emerging innovations." (Italics in original)

Culliton and Kennedy (2008): "An intellectual chasm exists between those who do innovative research and those who deliver it."

Gardner et al. (2007): "Unfortunately 'technological utopians' and 'systems utopians' seem to speak different languages; at

Figure 4 Elements of a global health research and innovation system



Source: Matlin and Samuels (2009)

worse, they compete fiercely for finance resources in the global health field.”

Interestingly, one argument as to why a focus on technologies and technological product innovation has dominated is the growth in one of the new organisational innovations. The strong presence of new organisational forms on the global health scene, notably the product development partnerships and global health initiatives such as the International AIDS Vaccine Initiative, PATH (formerly known as the Program for Appropriate Technology in Health) and Gavi, have pushed a focus on biomedical research and access to medicines at the expense of wider discussions on the enabling environment needed or the social innovation for health systems strengthening. The result is a continued dominance of debates by technological product innovations.

The emphasis is still on technological (product) innovations

A review of reports that have put forward solutions for global health problems in recent years (see Table 3) outlines the continued significant focus on technological innovation at the expense of social innovations.

The earliest report outlined in Table 3 is the Lancet Commission’s Technology for Global Health 2012 report. It takes a broad definition of technology as highlighted by the list outlined in Table 3. It refers to technology not just in terms of physical artefacts but also in terms of less tangible knowledge

associated with technologies. They define health-care innovation using a definition by Matlin and Samuels (2009) as “any initiative that takes novel ideas, inventions, or processes and applies them to achieve improved health and greater health equity” (Howitt et al., 2012: p. 4). However, only three of the technologies mentioned in the Lancet report move beyond tangible product innovations into the category of social innovations as defined in this report, namely: medical and surgical procedures, support systems and organisational systems. This leaves out a whole range of social innovation options that offers great potential for improving national health systems.

On the other hand, when discussing health related breakthroughs, the ‘50 Breakthroughs Report’ by Buluswar and colleagues at the Institute for Globally Transformative Technologies, Lawrence Berkeley National Laboratory only refer to what we consider to be technological product innovation. However, they do acknowledge that technologies (products) are not a panacea:

“technology is not essential to solving many of the problems surrounding global poverty. Tremendous progress can be made through institutional reform, infrastructure development, education, access to user finance, behaviour change, and other policy and social interventions. Indeed, even when technology is necessary, it cannot achieve meaningful impact on its own.” (LIGTT, 2014: 8)

Table 3 Solutions proposed for current global health problems

PATH's IC2030 30 most promising innovations (2015; www.ic2030.org)	
<p>Innovations for maternal, newborn, and child health</p> <ul style="list-style-type: none"> New formulations of oxytocin Uterine balloon tamponade Handheld device to measure blood pressure Simple, safe device for assisted delivery Chlorhexidine for umbilical cord care Kangaroo mother care New neonatal resuscitators New treatments for severe diarrhea Rice fortification New tools for small-scale water treatment Portable pulse oximeters to measure oxygen Better respiratory rate monitors <p>Innovations for reproductive health</p> <ul style="list-style-type: none"> Expanded access to implants and intrauterine devices Injectable contraceptives One-year contraceptive vaginal ring 	<p>Innovations for combating infectious diseases</p> <ul style="list-style-type: none"> Protective malaria vaccine candidates Malaria transmission-blocking vaccine Potent, single-dose antimalarial drug Expanded use of rapid malaria tests Broadly neutralising antibodies in HIV vaccines Long-acting injectable antiretrovirals Oral pre-exposure prophylaxis Novel multidrug treatment regimen for TB New vaccines to prevent TB Nucleic acid amplification tests <p>Innovations addressing noncommunicable diseases</p> <ul style="list-style-type: none"> Polypill Broader use of HPV vaccine Task-shifting for diabetes care mHealth innovations Portable, affordable screening for eye problems
LIGTT's 50 breakthrough technologies report (2014)	
<ul style="list-style-type: none"> Vaccines for HIV/AIDS, Malaria and TB Single dose/short course TB drugs Improved longer lasting ART Complete cure drug for malaria 'Clinic in a box' – inexpensive suite of integrated devices that make up key requirements for a clinic in low resource setting Automated and multiplex diagnostic immunoassays New long lasting, non-chemical spatial insect repellents Low cost portable, solar powered refrigerators New generation of homes with solar lights and toilets built in for urban poor Nutrient dense, culturally appropriate foods for infants to supplement breastfeeding 	
Lancet Commission's Technologies for Global Health report (Howitt et al., 2012)	
<p>Health technologies</p> <ul style="list-style-type: none"> Medical devices Biologics Drugs Medical and surgical procedures Support systems Organisational systems 	<p>Technologies for health</p> <ul style="list-style-type: none"> Agricultural equipment Bioengineered foods Road safety technologies Sanitation

Source: Authors

However, it then goes on to state that the report has decided to focus “on problems for which new technologies are critical.” It does not, however, appear to offer a justification for this decision.

The third report that we reviewed was PATH’s Innovation Countdown 2035 report (see www.ic2030.org). Again, this report lists a range of technologies; all but one of which is a physical product. The only technology going beyond technological product innovation would be that of task shifting in diabetes care.

The dominance of technological product innovation within policy reports over and above other forms of innovation mirrors arguments made in Chapter 2 with regards to the debates on definitions of health and ways of measuring the performance of health systems. As outlined in Chapter 2, these have often found it easier to focus on measuring progress in relation to burden of illness and disease at the expense of a number of wider issues such as the social determinants of health, including the presence or absence of a functioning health system.

The tide appears to be changing...

The reports that we have reviewed all come from the health policy field. Similar reports do not appear to exist from an innovation policy perspective. Therefore, to understand the exact nature of this separation, we conducted a wider literature review to determine how ‘health innovation’ as a concept has been considered in the literature and how this has changed over time. The literature review focussed on journals associated with either

public health or health policy and papers published in those journals from 2000, the year of the World Health Report focusing initially on health systems, to June 2015. The methodology of the literature review is outlined in Annex 1. Of the 220 papers that were identified between these dates, 93 were rejected after a review of their abstracts. This left 127 papers which were included in the review exercise.

The review found that 40% (n=52) of papers focused on low or middle income countries either through a specific country focus or as a result of focusing on global health issues more generally. The other 60% were focused on the global North, mostly focused on specific country level studies in the UK or US.

Surprisingly, just under 40% of the papers (n=47) focused on what we would term social innovation and what Gardner et al. (2009) describe as the organisation and distribution of health related goods and services. That said, few of them explicitly referred to this as social innovation. Only 16% (n=21) of the papers had an explicit, clearly specified focus on technological innovation, i.e. healthcare products (biomedical or IT mostly).

The review also revealed the following four subsets of discussions within the papers:

1 Diffusion of innovation

There were a set of papers (n=25) within the review which focused on diffusion of innovation, many of them referencing Roger’s theory of innovation diffusion (2010). Most of these focused on diffusion of technological innovation in European

or North American settings. However, eight of the papers were focused on innovation diffusion in low or middle income countries. This number is relatively high because a number of the papers are connected to each other being either studies from the same overarching project (PHIRE) or responses to a published letter, discussing diffusion (Baker, 2003).

2 Disruptive innovation

A much smaller set of papers discussed the role of disruptive innovation, including two papers (Hwang and Christensen, 2008; Smith and Christensen, 2007) involving Clayton Christensen who introduced the idea of disruptive innovation into business management analysis in the early 2000s. In total, 10 papers discussed disruptive innovation. The majority of these papers did this in the context of health systems in the global North. Two papers (Dandonoli, 2013; Sinha and Barry, 2011) discussed disruption in the context of global health. All the papers highlight the possibility of a set of innovations – some technological, some social – that could change – disrupt – the way healthcare is delivered. These range from the use of open innovation to cheaper technologies (such as the idea of a low cost ‘lab on a stick’) or social innovations that link to how doctors are deployed or care services are delivered.

3 Knowledge, learning and research

A further set of 11 papers looked at the relationship between knowledge and learning in the fields

of research and innovation. Often, this work was influenced by thinking from within the knowledge management field. As such, these papers are related at times to a broader discussion within the global health community on knowledge exchange, knowledge translation and knowledge brokering (see “Bridging the Know–Do Gap in Global Health” (2004) for an example of this literature). Much of the work in the literature search was focused on the high income country context and in all cases the emphasis was on how networks and collaborative exchange are necessary to enable the more difficult-to-access-knowledge that is harder to learn and transfer (tacit knowledge, learning by doing). One paper (Green, 2010) specifically talked about ‘systems level learning’ but the others implied the importance of organisational and systems related social innovation for ensuring successful technological development and the building of stronger health systems. Two of these papers (Walshe and Davies, 2013; Nwaka et al, 2012) discuss the importance of knowledge exchange and learning from the context of arguments on the benefits of scientific research. This relates to a set of arguments – much wider than expressed in this literature review – on the role of health research for improved innovation and strengthened health systems (as outlined in Chapter 2).

4 Innovation studies references

Even though this literature review only focused on journals that are associated with either public health or health policy, there is still a sizeable discussion

of innovation studies thinking in this material, and some thinking on systems type perspectives – often through implicit discussions of social innovations. Most of this refers to Roger’s diffusion theory or Christensen’s idea of disruptive innovation. However, another set of papers is linked to the health innovation system literature earlier described, while a fourth is influenced by the work in the health systems field on complex adaptive systems thinking.

The findings of the literature review highlight that the disconnects between the two fields of health and innovation can be, and are being, broken down. However, the pull of technological innovation to remain the major focus of many of these papers remains strong. Even at the height of interest in the health innovation system ideas, one of the papers reviewed (Morel et al, 2005a), in their discussion of health innovation systems, justify their paper by referring to the need for the formation of an Initiative for Health *Product* Innovation in low and middle income countries (our emphasis).

Summing up

This report focuses on the importance of using a broader definition of health innovation, which recognises not just technological product innovation but also social innovation. Specifically, it stresses

the importance of social innovation as a necessary determinant of successful technological product innovation. Such social innovations form part of any health innovation system as they have been described in the literature to date.

However, despite the increasing recognition of the importance of systems thinking in the health policy field (see Chapter 2) or the efforts of scholars who straddled the health and innovation fields (this Chapter), the emphasis of much policy and practice - indeed of much intellectual debate, too - is still heavily focused on technological product innovation.

The continued dominant focus on innovation only in terms of technological product innovation reduces the ability to consider innovation – social innovation in particular – with regards to health systems strengthening and efforts towards universal healthcare coverage. However, issues such as universal health coverage or improved financing for healthcare, which are increasingly recognised as also key for health systems strengthening, require not only technical solutions but also innovative institutional and organisational solutions; solutions that work to build system level strengths. The next Chapter, hence, outlines an approach that provides a means of investigating innovation at a health systems level.



4. Moving health systems strengthening forward: lessons from innovation systems thinking

Key points:

- 1 The building blocks of the health system need 'cement' to bind them together; social innovation provides this 'cement' through the creation of system building competences
- 2 Centrally important are knowledge (and politics) flows as determinants of systems strengthening
- 3 Active government and regulatory support for systems strengthening are important to ensure a facilitatory enabling environment whereby knowledge flows are promoted and politics flows are positive rather than negative in nature
- 4 Such an approach moves away from ideas of 'healthcare systems' to the idea of 'innovative health and wellbeing systems' for sustainable economic and social development

Chapters 2 and 3 have outlined the current state of thinking on health, innovation and health systems strengthening from the viewpoint of health policy, innovation systems and allied researchers

and practitioners to both of these fields. Specifically, the two Chapters highlighted how the discourse around these three concepts and their interconnections is often heavily focused on the starting point of technological product innovation. This is sometimes a very explicit focus as evidenced by the selective primary healthcare debates of the 1970s and 1980s or the more recent focus on global health partnerships to tackle the big three diseases of HIV/AIDS, TB and Malaria. Both of these debates focused on the role of drugs, vaccines and diagnostics in providing solutions to a nation's health problems. Alternatively, the discourse has focused more implicitly on technological innovation such as in the debates on health innovation systems in the early and mid-2000s and health systems strengthening more recently. While these have emphasised the need for wider approaches to the policy and practice landscape and the need for less siloed thinking, they are often still dominated by a narrow definition of good health as being absence of illness and dis-

ease, which may accentuate technological solutions over socially based ones.

These Chapters have, therefore, highlighted the need to start from a wider definition of health innovation; one that encompasses different forms of both technological innovation and social innovation. It has also placed this within the context of the need for a wider definition of health so that discussions can move beyond only curing illness and disease and look at wider concepts of well-being in the context of equitable and sustainable economic and social development.

As noted, there have been attempts to move beyond the siloed and narrow approaches and to encourage a more joined-up discourse. This includes the efforts of those who have advocated health systems strengthening and the need for increased health systems and policy research. It also includes those who have advocated for health innovation systems approaches at a policy level; including those from within the innovation systems community. However, discourses are heavily entrenched in these more narrow understandings of health, and focus predominately on technological innovation.

Thus, a question to be asked is:

Can innovation systems thinking provide any alternative ways of thinking about health systems strengthening that can allow policy and practice to effectively move beyond silos and disconnects towards wider understandings of health and innovation, so that systems become more functional and sustainable? We would argue that the answer is: 'yes'.

Four relevant elements of innovation systems thinking – the 4Fs

We would argue that there are four ways in which arguments from innovation systems thinking can assist in moving arguments forward in the field of health systems strengthening. These offer a potential lens through which to analyse health systems in order to find appropriate solutions to truly make health systems in low and middle income countries strong. We call them the '4Fs' of function, form, field and flows.

The first element of innovation systems thinking that can assist efforts to conceptually understand and practically analyse health systems strengthening is the philosophy of 'inclusive development', which is the starting point of most innovation systems thinking focused on low and middle income countries. Taking 'inclusive development' as the end goal of any development effort moves the debate beyond a narrow focus on good health. It puts sectoral issues into a wider perspective and ensures a focus on equity across all discussions.

In being the starting point for all discussions within innovation systems thinking for low and middle income countries, the notion of 'inclusive development' becomes the ultimate goal of innovation efforts in these contexts. As such, sectoral issues are channeled into meeting this goal and not simply meeting their own individual goals or the goals of individual profit making firms. Thus there is a need to recognise the wider **function** of health systems. Taking this one step further, when considering a wider set of functions, moves debates on

health systems towards thinking even more widely to ‘health and wellbeing systems’ and how these leverage improved economic and social development in the country.

The **second element** of innovation systems thinking is its recognition of the multiple actors involved in technological and social innovation. Specifically, this thinking highlights how the **form** that health and wellbeing systems take is determined by the actors involved; who they are and how they interact and collaborate. In other words, the forms of organisations that are created. This thinking does not only focus on private sector actors or on firms, although a lot of the literature has focused on this level. Innovation systems thinking recognises the multitude of actors who influence innovation activities, including the role of users, the role of the state and the role of private not-for-profit actors.

The **third element** of innovation systems thinking that is useful here is the recognition of markets and other institutions as determining the **field** in which any activity takes place. Particularly useful here are arguments that have been made which recognise that efforts to promote strengthened health systems often follow the logic of industrial activity, to paraphrase Gadelha et al. (2013). This resonates with a set of arguments already well known within the health policy field which argues that the health systems of many countries is becoming increasingly monetarised and commodified (c.f. Mackintosh and Koivusalo, 2005). That said, innovation systems thinking also recognises that while the market institution is important, a range of other institu-

tions, particularly the state and regulatory authorities, are also responsible for determining the success or otherwise of the systems actors in the efforts.

A **final**, and perhaps the most relevant, element of innovation systems thinking for these discussions on health systems strengthening is the way in which the origins or creation of systems is conceptualised. It enables, thinking around what facilitates the ability of form and field to work towards the function of a health and wellbeing system and a country’s development goals. Innovation systems thinking fundamentally emphasises the importance of ‘system making connections’ (Chataway et al., 2009; Metcalfe and Ramlogan, 2005), through many forms of social innovation, and the role of learning and knowledge **flows** in this. Others argue that these connections and flows create a ‘learning culture’ within organisations and within the system as a whole in order for the functional goals to be met (Johnson et al., 2003).

Innovation systems thinking has been critiqued in the past (Dodgson et al., 2011 an overview of these critiques) for being very macro-level in focus. As such, it has been critiqued for not recognising the inherent politics and power that surround the micro-level processes of technological change (Weber, 2002). These originate in actors (field) and institutions (form) and are manifested through the knowledge and learning flows that are promoted, supported - or neglected. However, there is a body of literature that tackles this directly (c.f. Srinivas, 2012; Cozzens and Kaplinsky, 2009; Papaioannou, 2014) and which is a neces-

Table 1 Health policy discussions and development: From two overarching opposing approaches to an integrative alternative

Health as a means to economic growth	Health as a means to achieve social development and reduction of inequality	→	Health as an integrated element of and contributing factor to economic and social development built on equity and inclusion
Health as absence of disease	Health as wellbeing	→	Health as wellbeing
Firms and private sector as drivers	Role of other actors, especially state	→	Complex network of actors
Supply driven	Demand driven	→	Problem driven
Knowledge as STI	Knowledge as DUI	→	Multiple flows of knowledge and power (STI and DUI)
Health innovation as new products	Social innovation is key	→	Multiple types of innovation and combinations of innovations required

Source: Authors

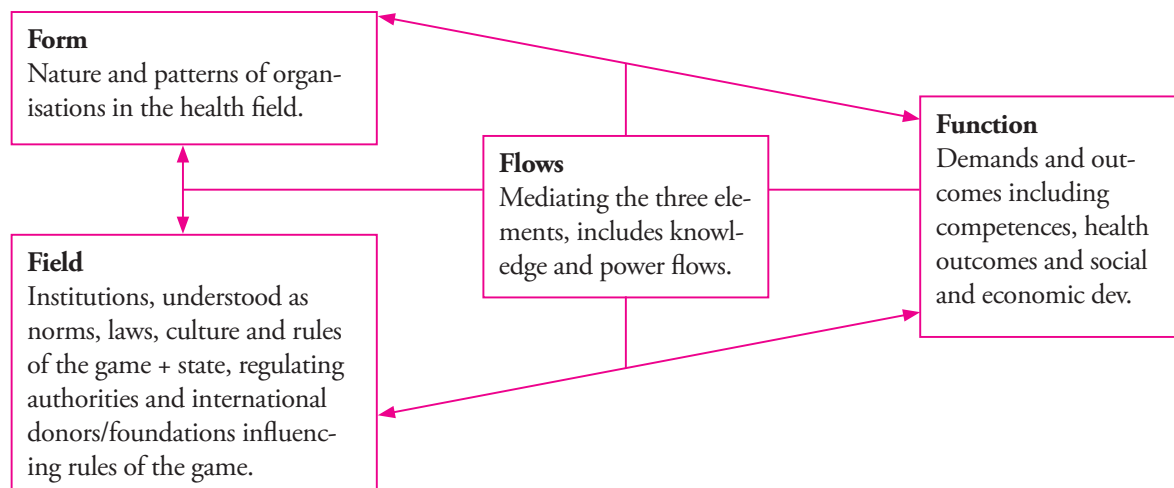
sary addition to ensure that the type, strength and direction of flows is best understood. Such flows determine the strength of the system making connections and degree and nature of knowledge exchange and learning that takes place.

The 4F’s as a lens for conceptualising strengthened health and wellbeing systems

Taking these 4Fs of function, form, field and flows together and using them as a lens for analysing the situation of current health systems in low and

middle income countries provides a way of identifying where to focus policy; especially in order to strengthen existing, and stimulate new, knowledge, learning (and positive politics) flows to support technological, but also and most importantly, social innovation, particularly of the organisational kind. This provides the ‘cement’ around which different elements – or ‘building blocks’ to use the WHO term – of the health and well-being system are created and promoted and ensure that they remain strong.

Figure 5 The 4Fs and their interlinkages



Source: Authors

Utilising the 4Fs as an analytical lens provides a means to move beyond the often-dichotomous debates outlined in the first two columns of Table 1 and focus on the last column's wider definitions of health and innovation; the complex and multiple connections, actors and institutions that are needed to create an innovative health and wellbeing system.

Thinking further on each of the 4Fs

Figure 5 provides a graphical representation of the 4Fs and their interlinkages. Below, we provide a further introduction to each of the 4Fs from an innovation systems perspective. We focus specifically here at the national level as the lens of analysis in

which to use the 4Fs. However, this does not preclude from recognising that form, field or flows maybe tied to other levels and beyond national boundaries. While, technically, a health and wellbeing system may exist at the community level, national level, regional level or international level, taking the national system as the starting point is key from a policy perspective. National governments are responsible for their citizens' health and wellbeing and for the economic and social development of the country. It is therefore at this level that the outcomes – the functions – of the system are best set. Even in situations where there is a devolved system of government (as in the case of Kenya below), national government still sets the agenda.

The function of health and wellbeing systems

The health problems facing the world are changing. Most notably, the rise of non-communicable diseases around the world is putting further stress on health systems in low and middle income countries that were already stretched trying to manage the infectious diseases and basic primary care services. There is also greater awareness of the linkage between health and social development – the need for good infrastructure (transport systems), housing, education and employment. The latter is especially important, both to ensure that people do not become sick in the first place or can afford health-care when they first need it, but also to ensure that stronger and healthier individuals aid/help in ensuring the continued functioning of infrastructure, housing, education etc.

Innovation is increasingly seen as a means not only towards economic development but also to health and social development. Innovation in this context isn't simply the production and delivery of new technological combinations but is also about innovation at a systemic level – the knowledge flows that create sustainability and ensure the system remains 'alive'. That being said, the core issue of interest is, ultimately, better health outcomes and inclusive economic and social development – the focus of attention and the ultimate aims of most activities in the health field. This implies taking a normative approach to development in which innovative activity in all spheres of activity is regarded as a necessary condition for develop-

ment.¹ Thus, the function of the system is two-fold: better health outcomes and; economic and social development.

Focusing on function in this way places an emphasis on ensuring a demand driven system rather than a supply driven one. The system must function to meet the needs of its customers, i.e. a country's citizens. Specifically, taking heed of the need to focus on outcomes, the idea of the 4Fs was developed in the spirit of the chain-linked model of innovation (Kline and Rosenberg, 1986) although still within a systems framework. In the chain-linked model of innovation, it is argued that market demand is the driver. Here we are defining the market in a very broad sense. In this context, for example, states effectively act as important drivers of demand, e.g. through public procurement of medicine and services for the sick, for children and the elderly.

The function of the system is the main driver of the system, although this doesn't mean the other elements are powerless. However, by focusing on function, it places an emphasis on demand instead of only focusing on the supply side as much innovation and health research and practice does. It acknowledges the role of users and their many different 'faces' in the 'market'.

1 We note that innovation doesn't always have a positive outcome or is used in a positive manner. This does not preclude the need to continue to promote innovation for the positive outcomes it can create.

The form of a health and wellbeing system

In this way, form follows function. Form refers to what some have called ‘patterns of organisations’ (McKelvey, 1982 cited in Rindava and Kotha, 2001) or what others talk of as the spectrum between markets and hierarchies (Williamson, 1975; Rindava and Kotha, 2001). Form refers to the organisations that are involved in different aspects of a health and well-being system. As such, this is about how healthcare and prevention is managed and provided and about the different actors involved in this process. It refers to the order of these organisations and the interactions between them.

Notably, it is about user-producer relations (Lundvall, 1985). In the innovation literature – and in the organisational management and economics literature – the focus has been mainly on firms, their interaction with others and how this affects firm performance. The innovation literature on user-producer relations is focused on the importance of the right kind of connections between firms and their customers. Specifically, work on the innovation performance of firms in the late 1980s, which appears to hold true today, suggests that vertical integration and hierarchy between a lead firm and a single professional user is not always the most beneficial; the “user who integrates with one specific producer excludes himself from access to interactive learning with the other producers” (Lundvall, 2016).

It is partly for this reason that the notion of a health economic industrial complex (Gadelha et al., 2013) has been proposed. It is argued that

this enables actors to move beyond the tensions “between economic and public health logics” because it recognises that healthcare services follow the “logic typical of industrial activity” (Gadelha et al., 2008) just as much as the production of drugs and vaccines does. Gadelha et al. (2013) argue that there is a need within this system for a ‘structuring entity’ to ensure all actors in the various sub-sectors of the complex function as required. They argue that the state must play a key role here as both healthcare provider, consumer, resource provider and regulator.

However, it is not only about describing the relationship between firms, public research organisations, ministries and other relevant organisations. It is also about rethinking them in terms of ‘problem solving organisations’ (Cozzens, 2010). Thus, Cozzens (2010) argues that instead of thinking about ‘firms’, we need to think about ‘problem solving organisations’. Instead of thinking about ‘research organisations’, we need to think in terms of ‘knowledge and information organisations’. Government’s role should be focused on governance and providing the right enabling environment. The result of which is embedded learning across society leading not only to better health but a stronger economy and potentially improved social cohesion.

The field of a health and wellbeing system

Problem solving organisations (form) and the problems they are working to solve (function) are impacted by the field. This essentially equates to institutions when defined in terms of norms, laws,

culture, rules of the game *a la* North (1990). However, it also includes organisations such as the state, regulatory authorities and even, in the world of global health, international donors who often ‘set the stage’ and define the rules of the game.

One key institution is the market. We have seen that discussions of health innovation are often focused on the development of technologies – new or improved vaccines, diagnostics and drugs. The argument would, traditionally, be that there is a case of ‘market failure’ whereby private sector firms are unable or unwilling to become involved in the market for health products. This argument is short-sighted for two reasons. First, market relations are embedded in the whole of the healthcare system leading some to argue that healthcare is becoming ‘commodified’ and ‘marketised’ (Mackintosh and Koivusalo, 2005). One of the arguments for this account of the current state of healthcare is that so much spending, especially in low and middle income countries, is done by individuals as out-of-pocket expenditure. However, in general, at a range of scales, health systems around the world are seeing numerous different exchange agreements in place that are based on someone ‘buying’ a commodity from someone ‘selling’ it; you have multiple layers of consumers – the patient, the doctor, the pharmacist, the medical supplier, the state, the pharmaceutical company.

A second major institution is the nation state and related regulatory mechanisms that are crucial because they set (national) standards and approval procedures for new products and processes and

their use in society. National governance of health issues vary considerably and is influenced largely by the political culture, leadership and visions in specific countries – including for example the perception of the importance of inclusive solutions and the extent to which healthcare is seen as a private responsibility versus a state responsibility (or a mix).

Flows

Mediating these three elements are the flows between them, notably knowledge flows creating learning cultures and learning organisations, but also power flows. Form and field can most effectively ensure that the system functions or meets its goals if there are sufficient, and the right sort of, knowledge and learning flowing within the system supported by positive (as opposed to negative) power flows.

There are three parts to knowledge and learning flows:

- 1 **Creation of knowledge and learning** – this relates to competence building. This is more than just the creation and distribution of knowledge through formal and informal training and education but more importantly the ‘doing, using and interacting’ (Jensen et al., 2007) of everyday experiential learning. As such, knowledge can be codified or tacit, it can be taught and transferred easily or it can only be learnt through apprenticeship and doing, using and interacting. The absorptive capabilities among individuals and in problem solving organisations and agencies to

be able to take up, utilise or transform knowledge are vital. They decide to a large extent how well new knowledge and innovations are taken up and their ability to contribute to better health and wellbeing outcomes.

2 Implementation of knowledge and learning – Knowledge and learning need to be promoted and utilised correctly. Any system should be more than the sum of its parts. What makes it more than the sum of its parts are the connections between the parts, but also knowing what connections are important and how to tap into the flows between those connections (Cohen and Levinthal, 1990). Key to successful innovation – of any type – is the learning and knowledge flows between parts of the system and recognition by actors that such knowledge is important.

3 System building connections – These relations make for an evolutionary and dynamic system where there is no equilibrium; the system is constantly evolving, creating winners but also losers. Thus, the issue is how to make the system function so that it becomes as equitable as possible through a focus on ‘system making connections’ (Chataway et al., 2007). This is important not least because of the continuous changes in the challenges experienced within the health field.

Power also flows through the system. While originating in the field and form of the system, this is linked to the promotion, creation and utilisation of knowledge and learning. With these comes ‘bias’ –

through action or non-action - which needs to be mobilised effectively (Bachrach and Baratz, 1962). Flows of power come with flows of knowledge. Key to ensuring the mobilisation of bias is the building of competences. Thus, it’s not knowledge per se that keeps systems functioning but actually the creation of absorptive capacity – the knowledge of how to take up knowledge, utilise and adapt it – across the system through ensuring that training and education are included. The absorptive capacity is essential for the take-up of new inventions and for inventions to become real-life innovations. For instance, increased knowledge about neurological issues and child development do no good unless actors in the wider system (ranging from parents over professional care takers to school teachers, psychologists and those working to improve the motoric of children, for instance) are able to take up this knowledge and use it in interaction with the children that they are responsible for.

Power in this way is not a social institution as per Bourdieu but has a much more complex role to play *a la* Foucault in that it is “diffuse rather than concentrated, embodied and enacted rather than possessed, discursive rather than purely coercive, and constitutes agents rather than being deployed by them” (Gaventa, 2003: 1) (Powercube, n.d.).

The important role that knowledge (and power) flows have on determining the success of a health and wellbeing system therefore suggests that what we need to build are not ‘health and wellbeing systems’, perhaps, but ‘competence building systems in the area of health and wellbeing’. Without such

systems, there will be little or no change of sustainability in the system. That said, sustainability does not come from a stable system but a dynamic system where each part is able to adapt and change to new situations; incorporating new knowledge and learning where and when needed. This requires the right set of competences. To build these, organisational change, supportive institutions and the right knowledge and power flows are required.

Sustainability – understood as the ability of the system to continue to change and adapt to new situations – is necessary if the outcomes of the system are to be met for the long term. In this regard, competence-building systems provide an opportunity for social and economic development to prevail.

Thus, the 4F lens, by moving beyond the disconnects between health and innovation and research or institutions and organisations enables us to ask different questions when analysing existing health and innovation system policies (please see overleaf). The questions focus on competence building across all the elements rather than simply on the need to build competences in health innovation that is only equated to the production of health technologies. This wider focus of analysis is essential for the building of stronger health and wellbeing systems.

Utilising the 4F lens to consider current health systems

As an example of the potential of the 4F lens we have conducted a review of two national health systems (Kenya and India) using the 4Fs as a means

of delineating different elements of activities going on within the system. Each country case starts with a brief introduction to the country context and is followed by a very brief overview of the key components and issues affecting health related activities in India and Kenya. The two countries have varying levels of maternal and child morbidity and mortality and are therefore at different stages in terms of progress towards meeting the SDG 3 on health. Both countries are classified as lower middle income by the World Bank. We focused specifically on Kenya and India because they are both still considered lower middle income countries, have a semblance of what anyone would easily recognise as a ‘health system’ in place and have an established local manufacturing sector involved in production of products for the health sector.

The details on each country are based on a review of key literature conducted for this report. The literature review was not comprehensive and therefore it is possible that the discussion below misses out nuances to the debates and situation facing each countries’ health and innovation actors. However, the review is not meant to be comprehensive at this point (further research is needed), instead, it aims to provide a preliminary idea of how this analytical framework might be used to review existing health and innovation systems policies.

The two case studies are presented below, one immediately after the other. A discussion of the issues raised by reviewing the health systems through the 4Fs takes place after these case studies are presented.

4F lens – key questions

Key questions originating from utilisation of the 4F lens

On function

- What are the needs of users – what are the health issues and the economic and social development issues that affect users?
- What are the system making connections that will build the competences needed to address both these health and development issues?

On form

- What are the problem solving organisations that are needed?
- How do these problem-solving organisations act as producers to meet user needs, through what organisations, and in what combinations (as formal or informal networks, collaborations or partnerships)?

On field

- What does the institutional landscape look like?
- In particular, what does governance within the system look like? So:
 - What is the role of the state as provider and consumer? What of other providers and actors?
 - Is regulation (including intellectual property rights) hindering or assisting form to follow function?
 - What is the role of policies from the state and/or other actors in the system?

On flows

- What knowledge flows through the system and how does it flow through?
- Is there a learning culture within the system?
- What are the power and politics that flow through the system? Does it hinder or support the creation of a learning culture?
- How do these flows influence implementation of health policies? How do they shape outcomes?

Reviewing India’s system of universal health coverage

India has significantly reduced the number of people living on less than a US dollar a day; by 56% (UNICEF, 2016). It also made significant progress towards meeting the MDGs. But challenges remain. Notably, it is increasingly having to deal with heart disease and strokes - now the leading causes of death, while cardiovascular disease is the second highest cause-of-disease burden (WHO, January 2015). Figure 6 outlines some key statistics relating to the health of India’s population.

In recent years, in efforts to meet the 2015 MDGs on health, India introduced a universal health coverage scheme specifically for states with

high disease burden. This provides increased clinic coverage and community health options (through traditional birth attendants and community mobilisers) and has done much to reduce mortality. But the focus has been predominately on doing what was needed to bring mortality down. Even then, there are still considerable problems related to poorly equipped or trained staff, low motivation of staff, and lack of trained staff.

In trying to understand why this is the situation, the relative emphasis placed on each of the 4Fs by policy makers needs to be analysed. The analysis below makes it clear that the starting point of recent health and more general country level economic and development social policy has been a

Figure 6 A snapshot of India’s health

Various health related world development indicators	Latest figures (year in brackets)
Life expectancy at birth, total (years)	68 (2014)
Under-5 mortality rate (per 1,000 live births)	48 (2015)
Maternal mortality ratio (modelled estimate, per 100,000 live births)	174 (2015)
Health expenditure per capita, current US\$	75 (2014)
Hospital beds per 1,000 people	0.7 (2011)
Nurses and midwives per 1,000 people	1.7 (2011)
Physicians per 1,000 people	0.7 (2012)

Source: World Bank database; <http://databank.worldbank.org/> (accessed 07/08/16).

focus on function and form at the expense of flows and field. By implication, future policies and interventions would need to consider issues related to flows and field more, in order to generate a more balanced and effective set of interventions in terms of ensuring better health outcomes and well-being in India.

Function

India developed a draft National Health Policy in 2015 which focused on provision of universal healthcare. Leading up to the development of this policy has been an increasing focus on universal health coverage (UHC) and the removal of rural-urban divides in healthcare through the creation in 2005 of the National Rural Health Mission (NRHM), which provided increased support to rural states that suffered the highest disease burdens.

India's economic development path has, traditionally, been focused through a series of five-year plans. In 2015, the government replaced the Planning Commission with the National Institution for Transforming India (or NITI Aayog). Its role is to design forward-looking plans for India's economic and social development, particularly relating to achievement of the SDGs. That said, the draft national health policy does recognise the two-way linkage between economic growth and improved health.

Form: context and institutions

The NRHM has been implemented through three major initiatives plus a series of additional activi-

ties (for a good overview, see Patel et al., 2015). There were three major initiatives. The first was a conditional cash transfer scheme whereby pregnant mothers receive a cash payment (to help pay for the delivery) in return for attending a public health institution to give birth. The second major initiative revolved around increased community involvement in health service provision through the support of village health and sanitation committees and training and support of an accredited social health activist (ASHA). The ASHAs, in particular, are seen as the link between the community and the health services; providing the community, particularly pregnant women and new mothers, with health advice and support. The third initiative has been more recent and sees the introduction of free basic hospital services to vulnerable groups through the introduction of a health insurance scheme. Alongside this third initiative, the National Rural Health Mission has been renamed the National Health Mission with a widening of its mandate to cover also urban India.

Field

The introduction of the NRHM and, more recently, efforts towards universal health coverage through a government health insurance scheme grew out of calls to reduce the rural-urban health divides and to reduce in general the levels of maternal, neonatal and child mortality and morbidity in the world's second most populous country. The NRHM was the result of efforts by a new government in 2005. More recently, efforts to increase universal access

have been the result of high profile efforts, including a series of high profile papers in *The Lancet* on universal health coverage in India culminating in a call for action (Reddy et al., 2011).

Efforts to implement healthcare activities in India are helped, and hindered, by a variety of institutional arrangements. A review of the literature highlighted the following issues (which do not make up an exhaustive or necessarily authoritative list but rather an illustrative one):

- A Commentators have remarked on the role of public services and the difficulties they face, including inefficiency and lack of accountability further hindered by the distance and size of populations and states. While devolved service provision has improved this situation, the latest healthcare reforms are unable to address structural inefficiencies in the wider system (Singh, 2008) with the existence of a big gap between the expectations that came with devolved healthcare and the reality on the ground (Seshadri et al., 2015).
- B Others have remarked on the over-reliance on and the strength of private healthcare providers (Bali and Ramesh, 2015;) and, linked to this, the development of a strong indigenous pharmaceutical sector in India (Kale and Little, 2007) and the strength of business-based lobby groups (Papaioannou et al., 2016).
- C Similarly important, though, have been patient lobby groups (Ebrahim et al., 2013) and international debates on the governance of health and

the need for universal health coverage within the context of health systems strengthening (Reddy et al., 2011; Patel et al., 2015).

Flows

Human resources for health are acknowledged as being key to the functioning of a health system (Lancet, 2008 and 2016; WHO, 2006) and an innovation system (Castellacci and Natera, 2013). They have also been acknowledged as a critical factor in the difficulties currently facing India's health system; specifically the sheer numbers required in such a populous country (even when admission rates to training institutions are at record levels) and their uneven distribution (Patel et al., 2015). Debates and resulting power flows at an institutional level outlined above have affected knowledge flows in terms of decisions taken with regards to the numbers and type of human, technical and financial resources available for the Indian health and wellbeing system.

Kenya's efforts to improve the quality of, and access to, healthcare

HIV/AIDS is the single largest cause of death in Kenya (14%) followed by predominately childhood diseases (ARI, diarrheal disease, malnutrition and birth complications) (WHO, 2015b). Figure 7 provides an overview of some of the data on Kenya's health system.

Kenya is similar to India in its movement in recent years towards achieving universal health coverage. In recent years, the government has reformed

Figure 7 A snapshot of Kenya's health

Various health related world development indicators	Latest figures (year in brackets)
Life expectancy at birth, total (years)	64 (2014)
Under-5 mortality rate (per 1,000 live births)	49 (2015)
Maternal mortality ratio (modelled estimate, per 100,000 live births)	510 (2015)
Health expenditure per capita, current US\$	78 (2014)
Hospital beds per 1,000 people	1.4 (2011)
Nurses and midwives per 1,000 people	0.9 (2011)
Physicians per 1,000 people	0.2 (2012)

Source: World Bank database; <http://databank.worldbank.org/> (accessed 07/08/16).

its National Health Insurance Fund (NHIF) which has been in operation since 1966. However, the scheme and healthcare services in general suffer from a series of constraints due to lack of resources as well as the growing dominance of a private sector that is difficult to regulate.

The analysis of the function, form, flows and field of health issues in Kenya undertaken below reveals that the situation in Kenya is less clear cut than the Indian situation due to multiple players influencing the field which, together with the resource shortages (human, material and financial), impact on the flows of knowledge and politics within the system. This has implications for future directions and policies.

Function

The right to health was enshrined in Kenya's 2010 constitution, which states that every citizen is entitled "to the highest attainable standard of health". The relationship between health and economic and social development has been acknowledged in Kenya's development strategy, Vision 2030. In this strategy, the country is tasked with strengthening social dimensions of society as well as the economic and political dimensions to improve quality of life and move the country out of poverty. It outlines science, technology and innovation as one of a number of enablers towards achieving the different elements of the economic, social and political pillars or dimensions of society.

More recently, the Kenya Health Policy 2014–2030, gives overall direction to health officials in the country to meet the requirements of the constitution, Vision 2030 and 'global commitments' (GoK, 2014). The key objectives of the health policy are to: Eliminate communicable conditions; Halt and reverse the rising burden of non-communicable conditions; Reduce the burden of violence and injuries; Provide essential healthcare; Minimise exposure to health risk factors and; Strengthen collaboration with private and other health related sectors.

Form

There have been two major activities that have re-defined health services in Kenya in recent years as the country aims to meet the various developmental and health objectives that the government and global leaders have set. As Obare et al. (2014) write, "[t]he most significant strategies in relation to UHC are the two attempts to transform the country's NHIF into a compulsory social health insurance. The objective of these proposed amendments was to shift the current health financing arrangements to prepayment mechanisms, reducing the dependence on out of pocket payment and mobilising more funds into the health sector through membership contributions."

The NHIF scheme offers outpatient services to all those enrolled. Every employer is mandated to enroll their employees into the Fund. However, public health facilities covered by the scheme are frequently affected by human resource constraints

(strikes, walk-outs and lack of trained staff) and supply side challenges (stock-outs of essential drugs and materials).

Furthermore, the majority (two-thirds) of the health facilities that are enrolled with NHIF are private (<http://www.jointlearningnetwork.org/news/the-road-to-universal-health-coverage-in-kenya-a-peek-at-key-nhif-reforms-t>). Private health facilities are the dominant source of medical treatment for Kenyans and significant out-of-pocket expenditure is still required. A 2014 report (Private Sector Innovation Programme for Health (PSP4H), 2014) found that the private sector provided 53% of health services in Kenya, the use of private insurance firms (particularly for those with higher incomes) and multiple problems with regulation of the sector. Out-of-pocket expenditure on health is currently estimated at 26% of household expenditure (GoK, 2013).

Kenya's health research and innovation system is characterised by a multitude of actors from the public, private and not-for-profit sectors as well as a rising number of public-private partnerships and significant donor engagement. The country has a burgeoning indigenous pharmaceutical sector (Kariuki et al., 2015) and some research institutes with an increasingly international reputation for conducting high quality health research (Whitworth et al., 2008).

Field

The health and innovation sectors are heavily politicised in Kenya. Health was an election issue in 2013

with the current President's campaign manifesto pledging universal access to free treatment (Green, 2013). It has since been further complicated by devolution. While decentralisation has often been argued (see Nyikuri et al., 2015) to provide opportunities for enhanced primary healthcare services as a result of service provision becoming the responsibility of local government authorities (county governments in the case of Kenya), the case in Kenya has been mixed. The Kenyan Health Sector Services Fund (HSSF) (supported by GoK, Danida and World Bank), which is the funding mechanism through which money is transferred to local communities for health services following devolution, has been heralded as a case study of success by those campaigning for Universal Health Coverage (Ramana et al., 2013). However, a more recent study of the impact of devolution on primary healthcare in Kenya (Nyikuri et al., 2015) found that success was much more dependent on the leadership capabilities of individuals, notably their soft skills in relationship building.

The fight between different policy sectors for a portion of the government's budget also affects the Kenyan health system. The latest figures published by the Kenyan government (GoK, 2012) show that the health sector received just 6.1% of government budget. This is much less than the 15% commitment that the government made in 2001 when it signed the Abuja Declaration on Health (Green, 2013).

The institutional landscape in Kenya's health sphere during 2013/14 was dominated by a Health

Sector Wide Approach programme (SWAp) which ensured coordination of all stakeholders through a single programme. With the creation of a new health policy, the SWAp is being replaced from 2013 by a Health Sector Intergovernmental Consultative Forum (HSICF) with funding channelled through two basket funds, the HSSF and a similar fund for essential medicines.

Flows

Much of the discussion in the literature has focused on the shortage of health workers and quality of training of healthcare workers. The exception to this has been two papers that have looked at the importance of strengthening the leadership skills of health workers (Nyikuri et al., 2015 and Le Rue et al., 2012). Interestingly, these papers make use of elements of organisational theory as part of their conceptual frameworks. A paper reviewing the first three years of the HSSF also highlights the importance of another soft skill, financial management expertise across the health sector (Waweru et al., 2013). Finally, there has also been a focus on reclassifying and task shifting and bringing in traditional healthcare providers (in a move similar to that in India).

Not specifically focused on in the literature or policy discussions per se, but alluded to above, is also the issue of political flows following devolution in Kenya; the management of multiple actors in the field since the regulation of private providers; arguments regarding division of public expenditure across sectors; and managing the demands of

donors as opposed to government objectives in the functioning of the HSSF.

Discussion

There are several issues raised by the review of the health systems of India and Kenya through the 4F lens:

1 The function of health related activities – wider thinking needed

In both examples, efforts in the field of improving health is predominately focused on reducing morbidity and mortality through expansion of health services, improved access to health services and increased efficiency. There is some attempt to link health to economic development and to recognise the place of innovation in the development of improved healthcare.

Wellbeing is absent from policy objectives, although it should be acknowledged that while reviewing the literature, wider definitions of health and the importance of social determinants of health is acknowledged.

The emphasis in these high level objective discussions on issues of system making connections is made, but tangentially, through recognition and goals relating to more efficient and functioning components of the health systems; the health system building blocks. However, increased recognition of the system building connections is needed; these are the ‘cement’ that binds the building blocks of a

health (and wellbeing) system together and keeps them strong.

2 Relationship between health and other sectors of the economy is often missing

As noted, there is some recognition in the two case studies of the linkage between health and other sectors of the economy. For example, in Kenya where Vision 2030 explicitly links good health with improved economic and political development efforts. However, health policy and innovation or industrial policy do not mix.

In Kenya, the new health policy discusses innovation solely in relation to the development and access to health products and technologies. It does recognise the need to develop indigenous capabilities to produce essential medicines but does not discuss how this will be done or the linkages required with other policy mechanisms or arms of government, except in relation to enhanced collaboration with the food industry for better regulation of that industry to safe guard the nation’s health.

In India, a similar situation is found in the draft National Health Policy 2015. Innovation is referred to simply in terms of medicines production. It does recognise the need to build an ‘innovation ecosystem’ but only in this respect. In doing so, it does recognise the need for policy committees to be made up of representatives for multiple sections of government including the Department of Industry Policy and Promotion.

3 Human resources for health acknowledged, but not knowledge flows and need for a learning culture per se

In the case of India, it appears that efforts to focus on health systems strengthening have made the emphasis on form and function stronger; actors at the field level have intensified efforts and push for UHC. This is at the expense of developing the flows within the system.

The issue of flows is not just a problem of human resources for health per se (although this is a massive issue) but of making the best use of the resources available. It is this latter issue that many of the discussions are not focusing on. Uneven distribution of human resources is part of the problem, but the latter also consists in having or lacking a learning culture within the system, which will ensure that the system can operate even in times of scarcity. This is why the development of so-called 'problem-solving organisations' is so important.

4 Using power and politics to create stronger linkages

The two case studies highlight two elements of power and politics that appear in general to be used to explain the difficulties faced in the health systems of each country. In India and in Kenya, this is predominately with regards to the allocation of resources. In India, it often appears to be a matter of internal debate within state institutions but in Kenya the role

of external actors, especially donors, has been highlighted. Differences must be worked with – relationships have to be managed – in such a way as to create stronger linkages rather than weaker ones within the system; to provide the opportunity to create a learning culture. This requires a well-coordinated and clearly defined functioning government structure. It also requires willingness among external development partners to support national coordination and priority setting.

Summing up

This chapter has introduced a new lens for analysing health systems, which takes concepts and ideas from innovation systems thinking and adapts them to the health system context. It does this in order to provide a means of analysing health systems in a way that emboldens current debates about the importance of building systems competences. It does this by moving away from only focusing on health related actors, i.e. on health systems, and focuses on the need to build innovative health and wellbeing systems. In so doing, it focuses on the importance of more interaction across traditional sectoral lines (health, finance, education etc.) and the importance of building problem solving organisations within a wider learning culture. The two case studies given provide an illustration of the way in which the lens can be utilised but also highlight the continued siloed status of health systems building and strengthening efforts.



5. Conclusion and deliberations for policy

In an era when health problems are changing but not necessarily getting less around the world, efforts to enhance the functioning of systems of prevention and care for health and wellbeing continues to be essential. Health policy makers and practitioners around the world are focusing on the need to increase universal health coverage – to make health-care accessible and affordable to all – but this is only part of the solution. Recognition of the need for wider understandings of health that focus on wellbeing and recognition of its complex interplay with wider economic and social development – with livelihoods – is also increasing. Taken together, this report has called for a need to focus on strengthening health and wellbeing systems and not just health systems.

We argue that one way of doing this is to build on work from within the health field around systems strengthening and incorporate more ideas from within innovation systems thinking. We not only point to a need to focus on technological product innovations; these have resulted in mas-

sive reductions in mortality and morbidity around the world through the introduction of new drugs, vaccines and diagnostic tools. We are arguing for a need to focus also on social innovation; particularly the introduction of new organisational and institutional arrangements to the way that health and wellbeing are promoted and healthcare is delivered around the world; especially in low and middle income countries where disease burdens and poverty levels are highest. We have outlined examples of such social innovations in various places in the report.

Specifically, we argue that the promotion of health systems strengthening in low and middle income countries can be supported more effectively through a focus on four elements (the 4Fs) of thinking from within innovation systems thinking relating to function, form, field and flows. We argue that the last of these is the most important as it is the ‘cement’ that enables actors within different forms of organisations and the institutional field to perform more effectively towards the

Table 4 Innovation systems thinking, the 4Fs, for health and wellbeing systems strengthening

4Fs	Innovation systems thinking
Function	Focus on inclusive development as a starting point and on how that relates to health (and vice versa).
Form	Multiple actors determine system functioning; and, more importantly, how do they interact?
Field	Actors’ interactions are determined by the market, the state and other institutions. It is important for the state and regulators to provide a positive enabling environment for effective and efficient flows to occur.
Flows	The most important element, without which the system will not function effectively. The promotion of learning and knowledge flows are central throughout the system. Power and politics that flow (through form and field) determine the success of learning and knowledge flows.

Source: authors

achievement of the health and wellbeing system’s functional goals. The 4Fs and their underlying conceptual platform within innovation systems is recapped in Box 3.

These suggestions are not new. As outlined, some social innovations that promote learning and knowledge flow across traditional boundaries are already taking place in relation to strengthening of health and well-being systems. The report has also outlined the similarities in policy and academic thinking between the health and innovation fields in this area. The question remains, however, how can we move such action forward; or,

in other words, what next? This short concluding Chapter will address that question.

Deliberations for policy to widen the impact of systems thinking for health and wellbeing

Below, we outline three main areas of deliberation that we believe must be undertaken at a policy level if systems thinking and specifically relevant elements of innovation systems thinking are to be effectively incorporated into health policy discussions to create not just stronger health systems but stronger health and wellbeing systems in low and middle income countries.

However, these deliberations are predicated on two assumptions relating to the policy process perspective and the need for multiple policy processes to be involved. These two assumptions will be outlined before we turn to the deliberations for policy.

Assumption 1:
Change in perspective by policy processes

For the deliberations to be fully considered, a range of policy processes are required to fundamentally change their perspective. We would argue that policy discussions tend to be dominated by two types of questions:

- a How can money best be spent to achieve better health outcomes (which investments to make)?
- b What modalities are needed to achieve better health outcomes (which policies and mechanisms should be strengthened)?

Such questions are operationally important but they are not sufficient. It is important that they are set within contextualised knowledge of the situation in question. There are two ways in which knowledge should be contextualised. First, it is not possible to simply transfer knowledge from one context to another. Instead, there is a need to ensure that reflection takes place on similarities and differences between the contexts in question and the details of a policy activity to make use of lessons learned from other countries or contexts. Second, the policy process must recognise the value of learn-

ing and knowledge not just within what might be defined as implementation elements of the health and wellbeing system but also within the policy process of such a system. Learning cultures must be built across the board, especially through learning by doing, using and interacting. Implementers and policy makers alike must realise the need for learning and reviewing/adjusting policies, strategies and modalities in view of experience and in view of the rapidly changing conditions and contexts, influenced not least by globalisation and radical innovations/new technologies.

Assumption 2:
Involvement of multiple policy processes

The deliberations below are based on the assumption that policy discussions become less siloed. This requires a completely new way of thinking and acting in some country contexts while in others it requires a further and wider continuation of existing efforts. The report has emphasised the fact that improving health of populations links to so many other areas of development because of the interlinkages between health, wellbeing, livelihoods and development. Thus, it is not sufficient if the required deliberations take place only in the health policy sphere. It requires cross-fertilisation of ideas and exchange of ideas between policy spheres as diverse as finance and education, agriculture and energy. For example, science and technology policies should be mandated to not just foster economic growth but also improvements in livelihoods and wellbeing through an additional focus on, and

greater connection with those working in, health, education etc.

Areas of deliberation needing attention

What follows is a list of areas for deliberation or analysis by policy makers that provide a starting point for, or enhanced scrutiny of existing efforts towards, systems strengthening for improved health and wellbeing enabling social and economic development. These areas of deliberation do not provide answers; they provide further questions and issues from which to consider development of contextually focused solutions.

Deliberation area 1: Should investments be made in technological or social innovation?

A broad understanding of innovation including technological innovation *and* social and organisational forms of innovation is required. This is particularly important because technological innovation won't be successful without strong social innovation. Encouraging system-making connections is particularly important in order to ensure social innovations work towards the creation of improved technological innovations and vice versa. *Without a stronger emphasis on social innovations, a lot of the investments made in the development of technological innovations related to health may very well be a waste of time and resources.*

That said, technological innovation is still important. *Various 'breakthrough technologies' have enabled new capabilities and create huge improvements in health systems of low and middle income countries.*

The case of Cuba is an obvious example here of the creation of a symbiotic relationship between local technological innovation activities and their local health and wellbeing system, together with their efforts to become internationally competitive in the pharmaceutical sector. In the case of Cuba, this has been a very deliberate effort by government but, in other instances, this might be more about the opening up of windows of opportunity that had not been foreseen. Such '*disruptive technologies*' in other sectors (e.g. *mobile money applications*) have been found to change the way that whole sectors are defined, interact and the types of learning and knowledge that are important.

Deliberation area 2: Should investments be made in building local capabilities and, if so, how should this be promoted?

Breakthrough technologies and disruptive technologies will only be possible, however, if there is sufficient strengths in science and complex new technologies built in low and middle income countries and/or knowledge and skills on how to utilise them. This report has not focused in any depth on the issue of domestic pharmaceutical capability building, but it is an important issue, which needs tackling. This is an area where there is evidence – from medical devices in Pakistan to the production of active pharmaceutical ingredients in various African countries – that building local capabilities has a win-win effect on local healthcare systems as well as efforts to industrialise and strengthen economic growth in low and middle income countries. How-

ever, this requires a much stronger interaction between different elements of government and policy to ensure adequately trained staff and sufficient inputs to enable the production, delivery and use of these technologies. It also requires that the global intellectual property rights system allow such development to take place.

In many low and middle income countries, the lack of strengths in science and complex new technologies does not have to be a hindrance. As outlined in this report, some commentators within the innovation systems field in fact argue that the ability to solve health problems in situations of scarcity – whether of materials, skills or finances – creates opportunities for ‘frugal innovation’ and ‘innovation in scarcity conditions’. Therefore, while at the same time promoting the creation of traditional science and technology related capability building, it is important for countries to also *promote opportunities for frugal innovation. This requires much more recognition and promotion of problem solving organisations, the promotion of learning cultures at all levels and an acceptance of all forms of knowledge.*

There are various mechanisms that can be used to encourage the development of domestic production capabilities in technological products of any and all kinds together with the development of institutional arrangements to enable the creation of skilled labour and the promotion of learning, acceptance of all forms of knowledge and its transfer and uptake. Some of those mentioned in this report include social innovations, particularly financial in-

novations. *More analysis is needed of the potential of public procurement mechanisms as a means of promoting local capabilities.*

Deliberation area 3: How can policy and practice becomes less entrenched in silos?

A future focus at national – and global levels – should be on building competences and a learning culture that enables good use of resources for better health outcomes and well-being. This requires appropriate investments in capacity and competence development as well as a strong focus on community involvement at local levels. It is about systems level innovation at the level of policy discussions. This requires thinking about health as an integrated element of, and contributing factor to, economic and social development and making an explicit link to equity and inclusion. Health is not just absence of disease but also wellbeing, which implies that efforts outside the health system per se are required. *A multi-sectoral approach and breaking down of silos is essential.*

We have focused this report on building up functioning systems of health and well-being at a national level. However, these policy deliberations need to be considered not only by national level actors but also by regional and global level stakeholders engaged in promoting better health outcomes, wellbeing, livelihoods and economic and social development more generally. As already acknowledged, it is difficult to boundary a system, and while it is functionally useful to boundary a health and wellbeing system at a national level *to enhance*

the achievement of improved health and wellbeing within a national level population, policy and practice involve a wider range of actors, especially at regional and international levels.

There are multiple actors involved in the health, innovation and economic development of a country. This is further complicated by the interplay of national and global issues as well as by the competing demands of supply and demand (or producers and users, to use the language of this report). As a result, the use of “forgotten knowledge” relating to improvement of national systems for better health outcomes and well-being should be promoted. This includes a strong focus on national ownership and commitment and willingness by international funders to support national policies and systems rather than bypassing these.

What next?

We have already acknowledged the entrenched nature of policy and practice discussions and action that are making it difficult to ensure wider definitions of health, as well as innovation and systems strengthening becoming mainstreamed into discourse and practice. Yet, some authors claim that a ‘grand convergence’ is possible if sufficient financing and support is made available to low and middle income countries to reduce the differences in disease burden around the world (Jamison et al., 2013). However, others have acknowledged that this requires a closing of the gap between health

and innovation experts (c.f. Moran, 2016). As such, our report would seem very timely; in terms of both the current push to finally reduce the gap between the rich and the poor but also the increasing recognition of the need to reduce academic and policy siloes that exist.

Working on this report has highlighted three ways in which the breaking down of these siloes might be undertaken in order to effectively push forward efforts to build stronger health and wellbeing systems. Specifically, there is a need for the following action in order to move discussions and practice forward and reduce levels of entrenchment:

1 Support for more inter/multi/trans-disciplinary research and practice

One of the reasons why health and innovation have rarely successfully been considered together (or, for that matter, wider questions of the relative merits of economic development over other forms of development) is that academic silos entrench ways of thinking and acting in training and education for the future practitioners and policy makers of tomorrow. As such there is a need for more funding opportunities to bring together health and innovation researchers to conduct joint research that specifically focuses on building health and wellbeing systems through technological product and social innovation. Findings from this research must then be used in teaching and education.

2 Utilisation of a new analytical lens to investigate the current status of health systems in LMICs

The 4Fs framework outlined in Chapter 4 provides an example of a potential alternative lens of analysis. In the health field of the 1990s, Walt and Gilson's (1994) work on the 'Policy Triangle' led to a similar alternative approach to analysing health systems (focusing on content, context, process and actors) that has become relatively well utilised since then. The concept of innovation systems, similarly, when first suggested in the early 1990s, has over the years provided an alternative approach to analysing the enabling environment for innovation. A framework such as the 4Fs has the potential to move beyond the siloes of health and innovation and enable a wider analytical lens through which to focus on more than one set of outcomes and impacts across a range of sectors.

3 Sharing of lessons learnt: building a stronger research and practice learning culture

Finally, the report has highlighted the importance of not just technological product innovations but also the importance of social in-

novations. These need to be widely publicised, researched further and critiqued. Just as we have argued that it is important for learning to take place within the practice and implementation arenas of health and wellbeing system strengthening, such learning is important in the research arena, too. As part of the efforts to break down silos in terms of research and practice, a more open international research learning culture is also required.

4 Increasing interaction between academics, policy makers and practitioners

Finally, working on this report has also highlighted the need for new ways of interaction between academics, policy makers and practitioners. Again, this is not something new! However, with increased pressure on public institutions and policy makers, including reductions in budgets for keeping policy makers up-to-date with research results, there is dire need to make new knowledge available, and not just in scientific journals and books. This is important, but needs to be accompanied by more direct ways of interaction from increased use of social media to face-to-face encounters.



6. Postscript

This year's Globelics report is a welcome challenge to us to think a-fresh about our understanding of the relationship between research, innovation and well-being. Focusing on health, Hanlin and Holm Andersen highlight inadequacies associated with conventional frameworks for analysing both how research and innovation capabilities take shape and grow but also how they can be encouraged to best serve social needs. The report quite rightly notes the limitations of much research which is judged by conventional standards to be 'excellent' in translating to innovation. At the same time, it is also clear that technological innovation which may generate wealth may also not meet social need. Whilst all of that is true, it is also the case that research and innovation are essential to meeting the needs of low income populations in low and middle income countries; a focus on health systems without consideration of the role of innovation is also limited in the extent to which it can address critical health challenges in low and middle income contexts.

In addressing these issues, the authors of the report redefine health systems to include a broader focus on well-being and prevention and make clear that frameworks for thinking about innovation and innovation systems thinking must also be redefined and particularly must include a more normative and outcomes based orientation. Research and innovation involves a range of activities to do both with new research and innovation and adapting existing knowledge (Srinivas and Sutz, 2008).

The report lays out a very useful framework for helping us think about how both to understand and encourage the generation of research and innovation that will more directly meet health needs. The 4Fs (form, function, field, flow) can be used both to analyse efforts at innovating for wellbeing and health and to stimulating new policy initiatives that are conceived with reference to a broader framework. This thinking about the 4Fs and the way that they might inform and structure analysis is relevant to low and middle income countries

(LMICs) and also to high income countries (HICs) where barriers to a more holistic conceptualisation of health and wellbeing is also often evident.

The preface of the report revisits writing on technological innovation and learning in relation to health innovation activities. Much of this work derives from the Globelics community and is essential to taking forward an agenda which aims to enrich our understanding of how innovation takes shape and the kinds of knowledge needed to both increase innovation output and relate that output to social need. The preface argues that technological capability building in LMICs is essential to longer term ability to meeting global health needs and reviews thinking about how increased innovation might be achieved but also some of the obstacles to initiatives to build capabilities. There is a rich scholarship on this subject and it is continuously being enhanced by Globelics scholars and others, some of whom are focusing on health innovation and asking questions that can be used to explore the territory laid out by Lundvall, Hanlin and Holm Andersen. A recent book by Maureen Mackintosh and colleagues, for example (Mackintosh et al., 2016), points to numerous ways in which health and pharma R&D and innovation is happening in low income contexts and the ways in which policy makers and practitioners are viewing this activity as a part of broader efforts to address health and wellbeing needs.

Building on this annual report, I see one of our next tasks as a community as identifying ways to mainstream the findings and framework and to think about what might be the drivers of change.

The report correctly frames health and wellbeing as being a terrain in which both public and private actors are active. Although the constellation of actors differs across contexts, there is widespread and growing concern to find ways to bridge the aims and agendas of public and private sector across LMIC and indeed also high income contexts. The report also highlights the need to build bridges across the health, social and industrial sectors and to create commonly understood framings of the key problems and issues amongst key actors in public and private sectors. Hanlin and Holm Andersen make a compelling case for the benefits of thinking anew about the way we go about linking analysis and activity across these different domains.

Ultimately, the success of bringing about the changes advocated by Hanlin and Holm Andersen will depend on power and political will and acumen. It will depend on a commitment from national and international powers to develop institutional and technological capacity and capability to address health needs. There is no way to avoid the central importance of that commitment. It may be that power entrenched in existing private and public organisations resistant to change, and with powerful economic interests to defend, will prevent constructive development along the lines laid out in the report. It is impossible, however, to imagine that no change will happen. The context of desperate need for better health, the limitations of previous approaches to provide health solutions, a diversity of aims, ambitions and interests and of public and private health product and

service providers looking for new models, will all provoke change.

From this angle, our work can be seen as an effort to identify the spaces and mechanisms for pushing forward an agenda for capacity and capability building based on an understanding of the type of frameworks and tools needed. Techno-fixes, or quick fixes of any kind that do not recognise the vital underpinning of institutional development including a supportive environment for learning and competence building at different levels, are doomed to failure. But without analysis, strategies and plans such as those being developed in this report, understanding of power imbalances will not inspire positive change either. As much as anything else, the framework and agenda for change laid out in this year's report is a political project. Political and social requirements for change should therefore not be ignored in future work that builds on this year's report.

Procurement: A possible driver of change?

One lens with which to consider further increasing linkages between different domains is the area of health procurement. The potential role of value based pricing (VBP) mechanisms is a subject that is increasingly high on policy agendas in high income countries. Procurement is important to think about because efforts to lower the cost of healthcare and derive greater value for public and private payers and patients is currently one of the main drivers of change in healthcare. Over the past few decades, pharmaceutical companies have found

it increasingly difficult to compete on the basis of R&D productivity alone and are looking for new ways to establish advantage and this has also contributed to keeping discussion of VBP's potential on the agenda.

Value-based pricing (VBP) is seen by some as a flawed approach that does not acknowledge the particular characteristics of health products and the underlying interests of health innovators (Arzymanow and Manning, 2013), but for others it represents a possible, although not unproblematic, route to achieving a common framework for valuing the contribution of drugs and technologies in different contexts (Persson et al., 2012; OECD, 2013; Sussex et al., 2013). In Europe, Sweden, Italy and Portugal, amongst others, have developed VBP based schemes and the debate about how pharmaceuticals and medical technologies are valued has occupied centre stage in policy debate about health innovation during recent years. Although Brazil's attempt to link social policy and health innovation policy has not been traditionally thought of as coming under the VBP rubric, it shares many common characteristics with VBP approaches.

In my view, VBP is a mechanism that can be thought about as a way of trying to incentivise the common framing of how to value innovation in different contexts. I say this not because I am convinced that VBP is a proven mechanism, or because I am unaware of the political or technical difficulties involved, but because the need for new ways of envisioning the connections between domains and for creating a common view of value is clear. VBP

may offer a route to that common valuation, or at least discussion of the need for approaches that hold a spotlight to value designations, and it could constitute a driver for introducing some of the changes advocated by Hanlin and Holm Andersen.

Value-based pricing is an umbrella term used to describe a variety of approaches to determining the value of new pharmaceutical innovations and other health interventions. VBP approaches are significant because they shift the attention of procurement policy from a standardised and often crude Quality Adjusted Life Years (QALYS) derived patient level assessment of price to a measure that also encompasses factors beyond individual health improvement, i.e. differential pricing according to a drug's performance in relation to health benefits to distinct groups of patients (distinct either with respect to physical or social and economic differentiation) and its impact on particular healthcare and social pathways and systems. In the latter context, this may require rethinking healthcare systems. A new medicine, or therapeutic intervention, might yield benefits to certain patients but might necessitate heavy involvement of clinicians and nurses, and using a VBP approach implies that the value determined by payers would reflect the overall cost and benefit of the drug to individuals and to the health system, and perhaps society more generally. On the other hand, a new treatment implemented in a certain way might reduce health and social care costs significantly and that benefit would also be reflected in the price under VBP arrangements. Some VBP schemes

take impact on industrial structure into account and thus incorporate consideration of development of industrial and innovation capabilities directly into reimbursement strategies.

The opportunities are also significant for pharmaceutical companies in that VBP mechanisms can provide stronger incentives to redirect resources in R&D, whilst improving their ability to differentiate their pharmaceuticals against competitors through higher value achievement. A range of new agreements have been established on this basis. For example, Proctor and Gamble provided provision to reimburse insurance companies in the US in cases where Actonel, their osteoporosis drug, failed to meet a range of clinical expectations. AstraZeneca and Pfizer are implementing plans for real-world data gathering about drug performance in clinic that will allow for new approaches to payment and procurement packages (Deloitte, 2012). At a national level, Sweden is one of the countries that has invested heavily in real-world monitoring of health innovation performance over time.

Both LMICs and HICs are grappling with rising healthcare needs and funding constraints. Both sets of countries need to find ways of incentivising innovation while sustaining effective market relationships with national and international industrial suppliers. This implies finding some way to deal with competing valuations among stakeholders and populations of the options available. They confront these challenges with a backdrop of acute population inequality reflected to a greater or lesser extent within healthcare (Jayadev and Stiglitz, 2009; Ag-

garwal et al., 2014). For manufacturers and health-care funders, pricing of medicines and technologies is a focus for conflicts of interest but also an emerging arena for collaboration.

Procurement using VBP potentially supports R&D whilst incentivising pharmaceutical firms to compete on a more socially beneficial basis. It can do this precisely because VBP expands valuations from cost-effectiveness measures, using calculations such as QALYs, to encompass wider factors such as health benefits to distinct groups, broader health system impacts, and social costs and benefits of treatments. One could imagine a scenario where it becomes the norm rather than interesting experiments for private providers to develop packages of care rather than simply products. Some packages could indeed include local production and innovation strategies in instances where this is called. Indeed, there is potential to go further and reward private and perhaps also public bodies to work together to provide care aimed at prevention and keeping people away from overloaded hospitals.

VBP also potentially represents a shift away from an “access to medicines” framework focusing on lowest cost procurement towards procurement incentives for cost effective innovation for patient benefit and with the overall health and care system performance in mind (Chataway et al., 2016; Nguyen et al., 2015). And, whilst ‘vertical’ approaches to addressing health needs on a disease-by-disease basis have delivered some successes, the same underlying need for overall health and well-being system development remains (Harman and

Williams, 2013). A refocusing of policy thinking towards incentivising industry-health linkages to improve health system performance is now visible in international debate (Sidibé et al., 2014; Mackintosh et al., 2016).

VBP approaches also chime with Hanlin and Holm Andersen’s call for a new definition of health and well-being rather than narrower definitions of innovation or health systems. A major issue, however, is that VBP, and perhaps any procurement scheme that aims to derive greater value from innovation, will rely heavily on real-world data collection. If this is a challenge in HICs, it is likely to represent even more of an obstacle in many LMICs. VBP, and value-based healthcare initiatives more broadly, also blur the boundaries between regulation and procurement, and raise largely unexplored and difficult issues at different governance levels. As indicated earlier, VBP schemes cannot be used to avoid any of the underlying issues around capacity and capability development, political will or governance complexity. They may simply offer an approach and mechanisms that can feed into and strengthen efforts.

While the HIC literature offers a strong theoretical case for VBP (Levaggi, 2014; Danzon et al., 2015), empirical evidence of its effectiveness is limited to a number of country cases (Towse, 2010; Persson et al., 2012; Sussex et al., 2013). Current debate in HICs focuses on the nature and scope of value criteria such as extending relevant costs of disease and treatment options beyond health services to those falling on other social services. The issue

of how valuations might be weighted to reflect the severity of illness and patient experiences at the end of life is a particularly difficult one (Rafferty, 2013). The issue of how VBP interacts with other pricing arrangements such as international reference pricing is also contested (Persson and Jönsson, 2015; Danzon et al., 2015). So, for all its potential and possibility it is important to recognise that there is no consensus on the inclusion of quality of life outcomes with social determinants outside medical care, or the impact of treatments on wealth generation.

These unresolved, often politically contentious and socially difficult, areas point to thorny issues that are at the heart of this year's Globelics report. Hanlin and Holm Andersen also notes that patients must be central to a problem solving approach and their views, needs and judgments must be configured into valuation of innovation, treatments and health/wellbeing frameworks. Patient views of VBP schemes are to date largely absent from considerations of VBP.

In summary, Hanlin and Holm Andersen stress the need to understand the complex and multiple links between social innovation and technological innovation. VBP offers potentially new ways to

include a broader array of stakeholder assessment for technology innovation and thereby could introduce a system of valuation that better represents the contribution of new products. VBP thereby constitutes one possible approach to forging new synergies between social and technological innovations. However, evidence is very limited on how 'value' is variously understood, what appropriate valuation metrics should look like, and how VBP might lead to realigned incentives in practice. Much more work could be done to establish the extent to which progressive VBP approaches are politically viable in different contexts and whether they can be useful in generating new framing of value of products and technologies across HIC and LMIC contexts in order to help build the kind of approach that Hanlin and Holm Andersen envision. Amongst many other ways in which the framework might be deployed, the 4Fs could potentially be used to help understand how VBP might work in different contexts and what opportunities and limitations might be associated with its introduction.

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Annex 1: Research methodologies

This report was written following an in-depth desk review of various literatures together with consultative talks with a number of different academics and policy makers. This Annex outlines the details of these activities in a little more detail.

Desk review

There were three elements to the desk review process. This involved a general overview of work that has been written on the subject – both academic and grey literature. It also involved a more defined literature review of both the innovation and health literature.

General overview work

This was conducted throughout the report writing process in order to provide a notion of the literature of a range of disciplines. The material read and reviewed forms the basis of much of the literature reviewed in Chapters 2 and 3 of this report.

The desk review consisted of a review of the global health and health innovation literature through a

review of four databases (Scopus, Web of Science, GoogleScholar and PubMed). A combination of the following search terms in these exact phrases and in various combinations of the individual words was used: ‘global health’, ‘health research’, ‘health innovation’, ‘developing countries’, ‘international development’, ‘learning’, ‘competence building systems’. In addition, a google search was conducted using the same search terms to find relevant grey material that would not have been available through the academic databases.

Each set of references found was reviewed and relevant literature read and integrated into the report as appropriate.

A literature review of innovation literature on health issues affecting low and middle income countries

A search of all Globelics conference papers and key innovation journals was conducted from 2000 to 2016 using the keyword ‘health’, filtering out those papers that focused on high income countries where the content was deemed irrelevant. This

material is utilised across the report but especially in Chapter 3.

An in-depth literature review of all health literature that discusses innovation and health issues affecting low and middle income countries

This consisted of a review of journal papers listed in ISI Web of Knowledge database from 2000 to 2015 that included the terms ‘health’ and ‘innovation’ in the title together with other databases as necessary. The material collected is utilised across the report and predominately in Chapter 2.

A very specific review was conducted of this literature. A decision was taken to utilise the ISI Web of Knowledge database as the most comprehensive set of journals across the two main fields: health and social sciences. The following search process was followed:

- 1 An initial search was made for papers that included the key words ‘health’ and ‘innovation’ in their title. This resulted in an initial list of over 1500 papers.
- 2 These papers were then further refined using the following parameters:
 - a English papers only published between 1st January 2000 and 30th June 2015
 - b Papers published in the top 20 ranked journals in the ISI citation index from public health and health policy sub-fields. Added to these, 22 further journals that are key

journals in the field of health systems and policy research.¹

- 3 A total of 220 papers were left for consideration after the parameters were introduced.
- 4 93 of these papers were rejected as not relevant following a review of their abstracts, were unavailable as full papers or were duplicates of another paper.
- 5 This left a final 127 papers, which were included in the review.

1 The final list of journals utilised contains: Health Affairs; Jama Journal Of The American Medical Association; Health Affairs Project Hope; Implementation Science; European Journal Of Public Health; American Journal Of Public Health; British Medical Journal; Lancet; Social Science Medicine; BMC Health Services Research; Plos Medicine; Bulletin Of The World Health Organization; Nature Medicine; BMC International Health And Human Rights; Nature Biotechnology; Global Public Health; The New England Journal Of Medicine; Health Policy And Planning; Sociology Of Health Illness; Journal Of Health Economics; Globalization And Health; Jama; Lancet North American Edition; Journal Of Health Services Research Policy; Human Resources For Health; Health Policy Amsterdam Netherlands; Implementation Science Is; Health Research Policy And Systems; Social Science Medicine 1982; Journal Of Health Politics Policy And Law; Science Or Health Policy; Value In Health; BMC Open; New England Journal Of Medicine; Lancet London England; Health Services Research.

Consultative process

The contents of the report have been discussed and ideas collected from members of the Globelics community and others as follows:

- 1 A two-day workshop involving 30 academics, mostly from within the Globelics community was held in Rio de Janeiro in March 2015 to discuss themes and issues to be discussed in the report.
- 2 The first draft of the report was reviewed by members of the Globelics Scientific Board and Secretariat in August 2015.
- 3 The draft report was circulated to a first round of four reviewers in September 2015. These reviewers were an even mix of innovation scholars and health policy scholars.
- 4 The main arguments of the report were discussed during a special session of the Globelics conference in September 2015 in Havana, Cuba.
- 5 The second draft of the report was circulated to eight further reviewers – two of whom were from outside of the Globelics community – in early 2016.



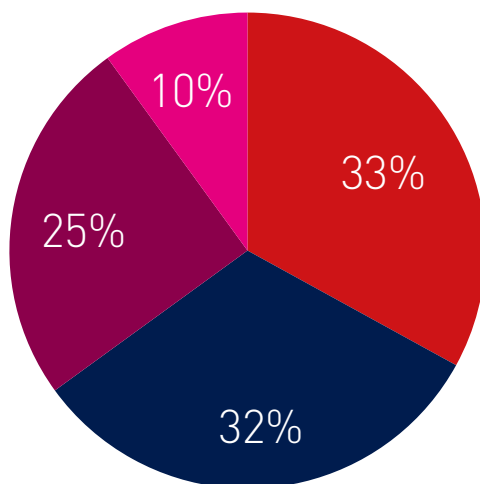
Annex 2: Globelics Conference papers referring to health issues in low and middle income countries (2006 – 2016)

The following is an analysis of papers on health from the Globelics conferences from 2006 to 2016. The conferences are:

- The 4th Globelics Conference, Trivandrum, India in 2006
- The 5th Globelics Conference, Saratov, Russia in 2007
- The 6th Globelics Conference, Mexico City, Mexico in 2008
- The 7th Globelics Conference, Dakar, Senegal in 2009
- The 8th Globelics Conference, Kuala Lumpur, Malaysia in 2010
- The 9th Globelics Conference, Buenos Aires, Argentina in 2011
- The 10th Globelics Conference, Hangzhou, China in 2012
- The 11th Globelics Conference, Ankara, Turkey in 2013
- The 12th Globelics Conference, Addis Ababa, Ethiopia in 2014
- The 13th Globelics Conference, Havana, Cuba in 2015
- The 14th Globelics Conference, Bandung, Indonesia in 2016

There is a total of 113 papers related to health from these conferences¹. By examining titles, keywords and abstracts of these papers, the distribution of papers among 5 categories are analysed. The categories are:

1 This does not include papers accepted for poster presentation.



- Institutional Innovation
- System Innovation
- Inter-organisational Innovation
- Process Innovation

- **Product innovations** – papers that discuss technological product innovations, i.e. papers that discuss the drug, vaccine or diagnostics development, the pharmaceutical innovation process etc.
- **Process innovation** – papers that relate to changes or innovations at intra-firm level, i.e. new or improved ways of managing people, processes in organisations etc.
- **Inter-organisational innovation** – papers about partnerships, networks, clusters, university-industry linkages etc.
- **Institutional innovation** – papers about governance or regulation related subjects, i.e. in-

tellectual property rights, innovative finance mechanisms etc.

- **Systems innovation** – papers about health innovation systems or related topics.

There are no papers in the category “Product Innovation” defined as technological product innovation. But there are papers on the conditions and strategies for product innovation. 11 papers (10%) are in the category “Process Innovation”, 28 papers (25%) are in the category “Inter-organisational innovation”, 38 papers (33%) are in the category “Institutional innovation” and 36 papers (32%) are in the category “System innovation”.

Complete list of papers on health from Globelics Conferences from 2006 to 2016 distributed by category

Process Innovation

- Alakärppä, Ismo and Valtonen, Anu (2010). Toward a Practice-Based Framework of Technology Acceptance: A Case Study on Bioactive Point of Care Testing. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Badarudin, Ahmad Ezainuddin bin and Abdullah, Zaini bin (2010). Using Balanced Scorecard as performance measurement system at private hospitals: making everybody happy, while taking care of the bottom line! Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Becerra, Lucas (2011). Learning and Insights from Management Technologies for Social Inclusion: A Socio-Technical Analysis Of The Drug Production Unit Of Talleres Protegidos De Rehabilitación Psiquiátrica De La Ciudad De Buenos Aires. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Engel, Nora (2011). New Diagnostics for Multi-Drug Resistant Tuberculosis in India: Innovating Control and Controlling Innovation. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Kale, Dinar (2013). Reconfiguration of firm capabilities from emerging country firms as a response to the emergence of biosimilar markets: Evidence from the Indian pharmaceutical industry. Paper presented at the 11th Globelics Conference, Ankara, Turkey.
- Madhavan, Harilal (2008). Knowledge origin, innovations and growth in ayurvedic bioprospection: references from Kerala. Paper presented at the 6th Globelics Conference, Mexico City, Mexico.
- Mohd-Nor, Rohaya (2010). Medical Imaging Innovative Features and Their Implications on Radiology Work Practices: Evidence from Malaysian Hospitals. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Rajan, Rony Thomas (2010). Organisational, Structural, Individual and Contextual Characteristics that can predict the adoption of Technology by a private for-profit hospital: A case of private for-profit hospitals in Kerala. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Santiago, Fernando (2012). Learning to do Pharmaceutical Innovation Drawing from Internal and External Sources of Knowledge: Exploring the Role of Human Resource Management Practices in the Case of Mexico. Paper presented at the 10th Globelics Conference, Hangzhou, China.
- Santiago, Fernando and Alcorta, Ludovico (2008). The influence of human resource management practices on learning and innovation: pharmaceutical firms in Mexico. Paper presented at the 6th Globelics Conference, Mexico City, Mexico.

Urias, Eduardo (2010). The Brazilian pharmaceutical industry: a co-evolution process between technology, institutions and industrial organizations. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.

Inter-organisational innovation

Chataway, Joanna Caroline; Banda, Geoffrey; Cochrane, Gavin and Manville, Catriona (2015). Innovative procurement for health and industrial development. Paper presented at the 13th Globelics Conference, Havana, Cuba.

Chataway, Joanna Caroline; Castle, Sophie Clarke and Wield, David (2014). Disruption and experimentation in health research and innovation: New building blocks and architectures for public and private sectors. Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.

Chataway, Joanna Caroline; Hanlin, Rebecca; Mugwagwa, Julius and Muraguri, Lois (2010). Global health social technologies: reflections on evolving theories and landscapes. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.

Contreras Romero, Carmen (2013). Social Networks, Location of Firms and Cluster Formation: A Mix-Method Study of the Biomedicine Sector in Chile. Paper presented at the 11th Globelics Conference, Ankara, Turkey.

D'Amore, Rosamaria; Iorio, Roberto and Stawinoga, Agnieszka (2010). The role of institutions and firm characteristics in the networks of firm publications. An analysis of the Italian biotech sector through the Social Network Analysis. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.

Ebrahimipour, Hosein; Dehnavi, Reza; Esmailzadeh, Hamid and Jafari, Mehdi (2006). The evaluation of University- Industry linkage in Medical Universities of Iran. Paper presented at the 4th Globelics Conference, Trivandrum, India.

Gutman, Graciela Elena and Laverello, Pablo José (2015). Early imitators in the context of the new technological paradigm: the (incipient) experience of Argentina's biopharmaceutical industry. Paper presented at the 13th Globelics Conference, Havana, Cuba.

Hanlin, Rebecca (2008). International product development partnerships: Innovation for better health? Paper presented at the 6th Globelics Conference, Mexico City, Mexico.

Hardiyati, Ria; Fizzanty, Trina and Aminullah, Erman (2016). Building Capacity For Innovation Through R&D Consortia In Health Projects: From Network Interaction To Systemic Transformation. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.

- Jasso, Javier; Calderón, Guadalupe and Torres, Arturo (2015). Innovation and academia-industry linkages in health. Multinationalization of companies in developing countries. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Kale, Dinar (2014). Where now for drug development innovation? Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.
- Kale, Dinar; Watkins, Andrew; Papaioannou, Theo and Mugwagwa, Julius (2015). Why industry associations matter in development of healthcare industries in emerging countries? Evidence from Indian biotechnology and medical device industries. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Lavarello, Pablo José (2011). Biotechnological Opportunities in Biopharmaceuticals And Firm Organization In Argentina. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Mantovani, Andrea and Naghavi, Alireza (2009). South-South Parallel Import and Cost Reducing Innovation in the Pharmaceutical Industry: An Alternative Approach. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Marjanovic, Sonja; Hanlin, Rebecca; Diepeveen, Stephanie and Chataway, Joanna (2012). Research Capacity-Strengthening in Africa: Networks, Institutions and Local Ownership. Paper presented at the 10th Globelics Conference, Hangzhou, China.
- McMahon, Dominique S. and Thorsteinsdóttir, Halla (2010). All the eggs in one basket: a look at regenerative medicine clusters in Brazil and China and India. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Niosi, Jorge (2011). Catching-up And Leapfrogging In Biopharmaceuticals The (Slow) Rise Of Emerging Countries. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Niosi, Jorge (2013). The Internationalization of Chinese and Indian Pharmaceutical Companies. Paper presented at the 11th Globelics Conference, Ankara, Turkey.
- Niosi, Jorge (2013). The Internationalization of Chinese and Indian Pharmaceutical Companies - challenges for internationalization theory. Paper presented at the 11th Globelics Conference, Ankara, Turkey.
- Pradhan, Jaya Prakash and Alakshendra, Abhinav (2006). Overseas Acquisition versus Greenfield Foreign Investment: Which Internationalization Strategy is better for Indian Pharmaceutical Enterprises? Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Ray, Monali and Thorsteinsdóttir, Halla (2008). Canada-India firm collaboration in health biotechnology. Paper presented at the 6th Globelics Conference, Mexico City, Mexico.

- Sampath, Padmashree Gehl (2010). Sectoral Systems for Health Innovation and Development. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Szogs, Astrid (2014). Investigating linkages with external actors: An analysis of three Tanzanian universities. Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.
- Thomas, Jayan Jose (2006). India and China in the Knowledge Economy: Rivals or Allies? Case Studies of Pharmaceuticals and Biotechnology. Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Thorsteinsdottir, Halla and Chaturvedi, Sachin (2014). An Analysis of the Impacts of South-South Cooperation: The Case of Health Biotechnology. Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.
- Thorsteinsdóttir, Halla; Kapoor, Andrew; Adly, Nefertiti; Aly, Sahar; Chaturvedi, Sachin; Konde, Victor; Ke, Wen; Li, Lexuan; Madkour, Magdy A.; Saenz, Tirso W. and Paula, Maria Carlota de Souza (2010). Changing Landscape of International Collaboration? A Study of South-South Collaboration in Health Biotechnology. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Torres, Arturo Torres and Villazul, Javier Jasso (2012). Research and Innovation in the Health Sector in Mexico: The Role of Public Research Organizations. Paper presented at the 10th Globelics Conference, Hangzhou, China.
- Vargas, Arturo Torres (2013). Social Mission of the University: A Case Study in the Health Sector in Mexico. Paper presented at the 11th Globelics Conference, Ankara, Turkey.

Institutional Innovation

- Abrol, Dinesh; Dhulap, Sivakami and Singh, Nidhi (2016). Foreign Firms, Product Patent and Pharmaceuticals in India after TRIPS. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.
- Abrol, Dinesh; Prajapati, Pramod and Singh, Nidhi (2010). Globalization of the Indian pharmaceutical industry: Implications for the direction, distribution and diversity in drug innovation. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Afolabi, Michael Olusegun (2012). A Disruptive Innovation Model for Research into Indigenous Medicines: A Perspective from Nigeria. Paper presented at the 10th Globelics Conference, Hangzhou, China.
- Bianchi, Carlos (2011). The role of innovation policies in the Brazilian biotechnology-health regime. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Bourgain, Arnaud ; Pieretti, Patrice and Zou, Benteng (2009). The Shortage of Medical Workers in Sub-Saharan Africa and Substitution Policy. Paper presented at the 7th Globelics Conference, Dakar, Senegal.

- Caliari, Thiago; Mazzoleni, Roberto and Póvoa, Luciano Martins Costa (2011). Innovation in The Brazilian Pharmaceutical Industry Post-Trips. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Chaturvedi, Kalpana and Chataway, Joanna (2006). Innovation in the Post-TRIPs Regime in Indian Pharmaceutical Firms: Implications for Pharmaceutical R&D Model. Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Chaudhuri, Sudip (2011). Re-Introduction of Pharmaceutical Product Patent Protection and Pharmaceutical Industry In India. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Chowdhury, Samik (2009). “Medical Poverty Trap” and the Urban Poor in India. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Chowdhury, Samik (2010). Health Shocks and the Urban Poor: A Case Study of Slums in Delhi. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Correa, Carlos M. (2011). Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Fiedler, Beth Ann (2009). Institutional Reform and Innovative Health Care Service Solutions via Microeconomic Intentional Community Business Development. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Guennif, Samira (2009). From TRIPS to “TRIPS Plus” provisions. Patents protection and public health promotion in developing countries: raising the stakes for drugs accessibility. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Guennif, Samira (2010). Intellectual property rights and other institutional matters influencing medicines accessibility in Thailand. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Guennif, Samira (2011). The Importance of Generic Drugs in the South: Behind the Brazilian Anti-AIDS Program, the Indian Performance in the Pharmaceutical Sector. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Habiyaremye, Alexis and Gachino, Geoffrey (2010). Optimal Patent Protection for Pharmaceuticals. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Hati, Moutushi (2006). Does the New Intellectual Property Rights Regime Impede Innovation in Developing Countries: A Case Study of The Indian Pharmaceutical Industry. Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Juncal, Santiago Eduardo; Mancini, Ezequiel; Lavarello, Pablo and Sztulwark, Sebastián (2016). Creative imitation in late industrializing countries: the case of biosimilars in South Korea and India. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.

- Kalarivayil, Rajesh and Desai, Pranav N. (2016). The Tale of Three Technologies: Examining Inequality in Health Research in India. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.
- Kale, Dinar (2013). Regulation quagmire, inclusive innovations and arrested development: evidence from the Indian medical device industry. Paper presented at the 11th Globelics Conference, Ankara, Turkey.
- Kale, Dinar (2015). New sources of growth under the TRIPS compliant patent regime for emerging country pharmaceutical industries? Investigating the development of biosimilar capabilities in the Indian pharmaceutical sector. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Nanda, Nitya; Barpujari, Indrani and Srivastava, Nidhi (2010). Securing Access to Patented Knowledge in Biotechnology: Can Patent Pooling Offer a Solution for India? Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.
- Ouma, Marisella (2006). Pharmaceuticals, Innovation and product patents; a lesson from India. Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Pandey, Poonam (2015). Visions and Practices of 'Technology for the Poor' in the Case of Diagnostics Development using Nanobiotechnology in India. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Ramani, Shyama V. and Urias, Eduardo (2013). Access to critical medicines: when are compulsory licenses effective in price negotiations? Paper presented at the 11th Globelics Conference, Ankara, Turkey.
- Rashmi, Rakhi (2009). Changed patent policy and biopharma innovation in India by foreign investment and technology transfer. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Rashmi, Rakhi (2011). Product Patent Regime and International Partnering For The Biopharmaceutical Innovations In India. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Sampat, Bhaven (2006). The Effects of Indian Pharmaceutical Product Patent Protection: An Analysis of the Mailbox Applications. Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Sampath, Padmashree Gehl (2006). Breaking the Fence: Patent Rights and Biomedical Innovation in "Technology Followers". Paper presented at the 4th Globelics Conference, Trivandrum, India.
- Sampedro, José Luis (2011). Knowledge Management from an Institutional and Evolutionary Approach: The Case of Telemedicine in Mexico. Paper presented at the 9th Globelics Conference, Buenos Aires, Argentina.
- Sutz, Judith (2014). Relation between innovation policies and social policies: Institutional arrangements for the promotion of innovation in health in Brazil and Uruguay. Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.
- Tomassini, Cecilia (2016). Economic and social orientations in the policies and programs to promote Science, Technology and Innovation in health in Brazil during the period 2000 – 2014. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.

- Urias, Eduardo (2014). The Brazilian experience on price negotiations for universal access to antiretrovirals drugs: a game theoretical explanation. Paper presented at the 12th Globelics Conference, Addis Ababa, Ethiopia.
- Urias, Eduardo and Furtado, João (2009). Institutional changes and their impacts on the Brazilian Pharmaceutical Industry: Is there an Innovation System on the way? Paper presented at the 7th Globelics Conference, Dakar, Senegal.
- Urias, Eduardo and Ramani, Shyama V. (2015). Access to medicines: A scoping study on the challenges of the current IPR system. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Vargas, Marco Antonio; Britto, Jorge and Szapiro, Marina (2016). Innovation and Public Procurement in the Health Sector in Brazil: a preliminary analysis of the Partnership for Productive Development (PDPs) program. Paper presented at the 14th Globelics Conference, Bandung, Indonesia.
- Wong, Lissy; Zaldivar, Dionisio and Vera-Cruz, Alexandre O. (2015). Barriers for the introduction of new products based on biomaterials in the Cuban health system: the case of TISUACRYL®. Paper presented at the 13th Globelics Conference, Havana, Cuba.
- Zhukov, S.S. (2010). Constitutional foundations of medical aid regulation: issues and trends. Paper presented at the 8th Globelics Conference, Kuala Lumpur, Malaysia.

System innovation

- Afolabi, Michael Olusegun (2009). Exploring the Technologies of Laboratory Science for Social Change: an Examination of the Nigerian Healthcare System. Paper presented at the 7th Globelics Conference, Dakar, Senegal.
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